NEW ENGLAND COMPOUNDING CENTER

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TITLE: POLICIES AND PROCEDURES	
SOP NUMBER: 1.010	**VERSION NUMBER: 2.0**
Non-Sterile and Sterile Laboratory	Current Effective Date 11/20/07
Originator:	
Reviewer: Barry J Cadd	

1.0 PURPOSE

1.1 The purpose of this policy and procedure (SOP) is to establish requirements for creating, revising, deactivating or performing annual reviews of SOPs at New England Compounding Center.

2.0 SCOPE

2.1 This procedure applies to all personnel at New England Compounding Center.

3.0 RESPONSIBILITY

3.1 The Pharmacist-in-charge or the Quality Control Officer shall supervise this procedure.

3.2 All personnel at New England Compounding Center are responsible for following this procedure.

4.0 REFERENCES

4.1 USP Current Version <797> "Pharmaceutical Compounding – Sterile Preparations"

4.2 USP Current Version <795> "Pharmaceutical Compounding – Nonsterile Preparations"

5.0 DEFINITIONS

5.1 Change Request Log Number – Unique number assigned to an SOP Change Request

5.2 Effective Date – Date on which a new or revised SOP is implemented

5.3 Master Copy – Original SOP document stamped "Original" and initialed/dated by the appropriate individual; can be used to make distribution copies (stamped "Copy") for SOP binders if necessary

5.4 N/A – Not Applicable

5.5 Deactivated SOP – SOP that is no longer in use

5.6 Review Copy – Printout of a new or revised SOP that is routed to the appropriate individual for review and comment

5.7 Standard Operating Procedure (SOP) – Controlled document with a unique identification that provides detailed instructions regarding a particular task

5.8 SOP Index – Document which provides SOP number, title, version number, effective date and review date

5.9 Training Copy – Printout of the approved new or revised SOP (without the effective date) that is routed for training purposes prior to issuance

6.0 FREQUENCY

6.1 SOPs must be reviewed and updated a minimum of once annually.

6.2 SOPs must be created, revised or deactivated as necessary.

7.0 EQUIPMENT & SUPPLIES

7.1 N/A

8.0 GENERAL INFORMATION

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8.1 The SOP number of an inactive SOP shall not be reused. All copies of inactive SOPs in SOP binders must be destroyed, and a designated individual shall maintain a separate binder for all inactive SOPs.

9.0 PROCEDURE

9.1 All policies and procedures within this manual follow the same format. Each policy and procedure will include, but will not be limited to, the following sections:

9.1.1 Title – A succinct description of the subject of the SOP

9.1.2 SOP Number – A unique number assigned to each SOP

9.1.3 Version Number – A sequential number assigned to each SOP

9.1.4 Originator/Reviewer – Signatures of all individuals approving the SOP (only appears on first page)

9.1.5 Effective Date – Date when the SOP is implemented

9.1.6 Page X of Y (optional) – Current page number followed by total number of pages

9.1.7 Purpose – Provides a detailed explanation of the reason for creating the procedure

9.1.8 Scope (optional) – Details the extent of, and limitation of, the SOP; may also detail the applicability of SOP

9.1.9 Responsibility – Defines personnel who shall be responsible for supervising and/or carrying out the procedure

9.1.10 References – A list of all documents that are referenced in, or must be used in conjunction with, the SOP (other SOPs, government standards, equipment manuals, etc.)

9.1.11 Definitions (optional) – A list of words not in common use including terms used in a manner specific to a particular SOP

9.1.12 Frequency – A list of events and the amount of times they should occur in a particular timeframe

9.1.13 Equipment & Supplies – Laboratory instrumentation, apparatuses and reagents utilized during the execution of the procedure

9.1.14 General Information – Any background/additional information that applies to the procedure; not required for execution of the procedure

9.1.15 Procedure – Step-by-step instructions for carrying out the procedure

9.1.16 Attachments – List of all attached forms required to document actions taken during the execution of the SOP

9.1.17 History – Chronological listing of at least the last three revisions; includes the previous version number, the date effective, a brief description of the revision and the change request log number

9.2 SOP Control Systems

9.2.1 All new or revised SOPs are submitted to the appropriate individual, who is responsible for approving all procedures, routing the document for other approvals, processing the final document and issuing the new or revised document.

9.2.2 After all approvals have been obtained and the documentation has been finalized, the SOP shall be issued.

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9.3 Initiating or Revising an SOP

- 9.3.1 New Procedures
  - 9.3.1.1 A new SOP may be initiated by anyone, and the Pharmacist-in-charge will evaluate the necessity for the proposed SOP.
  - 9.3.1.2 New SOPs will be assigned a version number of 1.0. This number will increment to the next whole number for each revision made to the SOP. Attachments of an SOP will have the same version number of the SOP. It is the responsibility of each employee to use the current version of the attachment.
  - 9.3.1.3 Obtain an SOP number and a change request number (see Attachment 3) from the appropriate individual and complete the SOP New/Change Request Form (Page 1 of Attachment 1).
  - 9.3.1.4 The change request number shall be "CRXXYYY," where XX is the last two digits of the current year and YYY is incremental beginning with 001. (For example, the first change request of 2005 would be CR05001.)
  - 9.3.1.5 After completion of the draft SOP, a review copy of the SOP will be printed out and routed along with the new/change request form and all other necessary documentation.
- 9.3.2 Revising A Current Procedure
  - 9.3.2.1 SOP changes shall be authorized by the same functional group(s) that approved the current version.
  - 9.3.2.2 Obtain a change request number (see Attachment 3) from the appropriate individual and complete the SOP New/Change Request Form (Page 1 of Attachment 1).
  - 9.3.2.3 Once revision is complete, the originator will notify the appropriate individual. A printout of the review copy is attached to the SOP New/Change Request Form and any supporting documentation, if needed to justify changes, is submitted as well.
  - 9.3.2.4 SOP review (annual) may be performed as part of the revision process.
- 9.3.3 The change originator shall complete the SOP Change Request Form, and, along with the Quality Control Officer, shall sign and date the bottom of the form.
- 9.3.4 The Pharmacist-in-charge shall determine who must approve the SOP.
- 9.3.5 All revisions made to the SOP review copy shall be documented in red ink along with the reviewer's initials and the date.

9.4 SOP Training

- 9.4.1 The individual submitting the new or revised SOP shall indicate the training requirements on the SOP Change Request Form.
- 9.4.2 Before issuing the procedure, training documentation must be on file (Read and Understand Form- Attachment 2).

9.5 Read and Understand Form

- 9.5.1.1 The SOP change originator will route the Read and Understand Form (Attachment 2) along with the final version of the procedure without a date effective and stamped "Training Copy" to all applicable personnel.
- 9.5.1.2 After all applicable personnel have signed the Read and Understand Form; the appropriate individual will issue the procedure per section 9.5.

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9.5.2 Training Session

9.5.2.1 The SOP change originator will provide the trainer with a final version of the procedure without a date effective and stamped "Copy".

9.5.2.2 The trainer will perform and document the training.

9.5.2.3 The appropriate individual will then issue the procedure per section 9.5, provided no additional training is required.

9.5 SOP Issuance

9.5.1 The SOP effective date will be added to the header and the change history table at the end of the SOP.

9.5.2 The master copy of the SOP shall be printed out. Each page should be stamped "Original," and the appropriate individual should initial/date the bottom of each page.

9.5.3 The SOP change originator shall update all applicable SOP binders with the new or revised SOP.

9.5.4 The SOP change originator will maintain a file folder for each SOP, which contains the current and historical signatures and any technical information that supports the SOP content or that justifies changes made.

9.5.5 The master copy of the replaced version of the SOP and all attachments are lined out and marked "Revised" and initialed/dated when the new original is placed in the master SOP file.

9.6 SOP Index

9.6.1 The appropriate individual shall be responsible for maintaining and updating the SOP index as changes are made.

9.6.2 The SOP index will detail the SOP number, title, version number, effective date and review date.

9.7 Annual SOP Review

9.7.1 Each SOP shall be reviewed annually to ensure the written procedures accurately represent the current practice.

9.7.2 The SOP review shall occur within one year, give or take three months, of the effective date or of the last review date.

9.7.3 The appropriate individual shall be responsible for maintaining an SOP Review Index, which documents when the last review was performed. The individual shall identify those procedures due for review.

9.7.4 Approximately three months prior to the review date, the appropriate individual shall initiate an SOP Review Form (Page 2 of Attachment 1), attach a copy of the current procedure to the form and forward the documents to the appropriate personnel.

9.7.5 The appropriate personnel shall review the SOP and determine if changes are necessary.

9.7.6 Page 2 of Attachment 1 must be completed for each review performed. At the end of the review, the reviewer shall indicate one the following as a result of the review:

9.7.6.1 "No changes need to be implemented."

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9.7.6.2 "SOP New/Change Request Form is attached to update the procedure, Change Request Log Number CR______________."

9.7.6.3 "SOP should be deactivated, Change Request Log Number CR______________."

9.7.7 The reviewer is responsible for initiating an SOP Change Request if changes are required or if the SOP should be deactivated.

9.7.8 The appropriate individual must maintain completed SOP Review Forms in a designated binder.

10.0 ATTACHMENTS

10.1 Attachment 1 – SOP New/Change Request Form (page 1 of 2)

10.2 Attachment 1 – SOP Review Form (page 2 of 2)

10.3 Attachment 2 – Read and Understand Form

10.4 Attachment 3 – SOP Number Log

10.5 Attachment 4 – SOP Change Request Number Log

11.0 HISTORY

Version Number	Date Effective	Description of Change	Change Request Number
1.0	03/07/06	New SOP	N/A
2.0	11/20/07	Changed wording and updated	CR07015

Remainder of this page intentionally left blank.

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SOP NEW/CHANGE REQUEST FORM – Attachment 1

(Page 1 of 2)

Check one: ☐ New ☐ Change **Change Request Log Number:** ______________

SOP Number/Title: ____

____

Version of SOP being changed: ____________________ **New Version:** ______________

Description/Text of Change: (see attached Changed Document)

____

____

Reason for Change Request:

____

____

Supporting Documentation: (mark one)

☐ None Required ☐ Attached → reference (specify): ____________________

Requested Implementation Date: (mark one)

☐ Less than 30 Days ☐ By Date: ______________

Annual SOP Review Requirements: (mark one)

☐ Complete review was performed to satisfy the requirements of SOP review (see page 2).

☐ Review limited to changes only, SOP review will need to be performed when scheduled.

Check Training Requirements: (mark one)

☐ Read and Understand Memo ☐ Training Session Required

Training Checklist:

☐ No Checklist is Required **OR** TC#__________ has been reviewed and:

☐ No Changes are Required

☐ Checklist needs to be Written/Changes are Required → TC change # ______________

Change Originator: ____________________ Printed Name ____________________ Signature ______________ Date

Quality Control: ____________________ Printed Name ____________________ Signature ______________ Date

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SOP REVIEW FORM – Attachment 1

(Page 2 of 2)

SOP Number/Title: ____

____

Date Effective: ______________ **Version:** ______________ **Last Reviewed:** ______________

SOP REVIEW – PLEASE CHECK THE FOLLOWING AS THEY ARE PERFORMED:

☐ Ensure that the purpose, scope, responsibilities, definitions, and general information sections are still accurate and current.

☐ Ensure that the responsible functional area groups are consistent with current organizational structure.

☐ Check references to ensure that they still apply, that the titles have not changed, and that the references to documents within the text are correct.

☐ Verify that all materials, equipment, reagents, etc. called for in the procedure are still available and are being used.

☐ Ensure that the current practice is reflected accurately in the procedure section of the SOP.

☐ Ensure that the procedure addresses what action to take if the task has unacceptable results.

☐ Ensure that all documentation requirements and storage/archival requirements are reflected in the SOP.

☐ Ensure that all attachments continue to be accurate and reflect current practices.

CHOOSE THE STATEMENT THAT APPLIES:

I have reviewed the above mentioned procedure and:

☐ No changes need to be implemented.

☐ SOP New/Change Request Form is attached to update the procedure, Change Request Log Number CR______________.

☐ SOP should be deactivated, Change Request Log Number CR______________.

SOP Review Performed By: ______________________________ Date: ______________

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READ AND UNDERSTAND FORM – ATTACHMENT 2

The following SOP is either new or revised. Please read the SOP. After you have read and understand the procedure, please sign and date the bottom of this sheet. By signing this document, you are indicating that you have read the procedure and that you understand the requirements of this procedure as it applies to your position. After everyone has had an opportunity to sign, please return this memo to the appropriate person for filing. Thank you.

SOP Number/Title: ____

____

SOP Version Number: ____________________ **Date:** ____________________

PRINTED NAME	SIGNATURE	DATE

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SOP NUMBER LOG – Attachment 3

SOP Number	SOP Title	Issued To	Issued By	Date Effective

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SOP CHANGE REQUEST NUMBER LOG – Attachment 4

Change Request Number	SOP Number/Title	Issued To	Issued By	Date Effective
CR__________				
CR__________				
CR__________				
CR__________				
CR__________				
CR__________				
CR__________				

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TITLE: DEVIATIONS – OOS		
SOP NUMBER: 1.030	**VERSION NUMBER: 2.0**	
Non-Sterile and Sterile Laboratory	Effective Date	03/13/2008
Originator:		
Reviewer:		

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1.0 PURPOSE

1.1 This policy and procedure (SOP) outlines the process to follow when a deviation from procedures and instructions occurs, whether before occurrence or after occurrence.

1.2 This procedure will describe how to identify, validate and assign corrective action, if needed, to an initial out-of-specification (OOS) result.

2.0 SCOPE

2.1 This procedure applies to all compounding personnel at New England Compounding Center (NECC).

3.0 RESPONSIBILITY

3.1 The Pharmacist-in-charge shall supervise this procedure and document that all personnel responsible for following SOPs will comply with this procedure.

4.0 REFERENCES

4.1 N/A

5.0 DEFINITIONS

5.1 Document – Information and its support medium

5.2 Quality Record – Original data that is the result of original observation and activity

5.3 Out-of-Specification (OOS) Results – All suspect results that fall outside the specifications or acceptance criteria established in drug applications or official compendia or specified by the manufacturer

5.4 Initial OOS – Any test result that is outside of manufacturer's specification, before assessment or investigation has been performed to validate results

5.5 Confirmed OOS – An initial OOS, which, after lab assessment, remains a valid OOS (failure)

5.6 Initial Lab Assessment – An investigation performed to validate an initial failed result; could include a retest of original sample to verify lab or instrument error

5.7 Method Deviation – An unplanned change in a portion or specific step of a procedure during execution of the procedure

5.8 Method Modification – A planned change in a portion or specific step of a procedure prior to its performance

5.9 Materials – Any raw materials or packing components used in the preparation of a product

5.10 Product – In-process or finished, regulated formulation; commonly referred to as a preparation, article or CSP (compounded sterile preparation)

6.0 FREQUENCY

6.1 When applicable

7.0 EQUIPMENT & SUPPLIES

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7.1 N/A

8.0 GENERAL INFORMATION

8.1 All deviation and modification forms will be filed in a Quality Control file.

8.2 Method Deviation/Modification numbers will be assigned as:

8.2.1 DXXYYY, where D is "Deviation", XX is the last two digits of the current year, and YYY is incremental beginning with 001and ending at 999 for the entire year.

8.2.2 MXXYYY, where M is "Modification", XX is the last two digits of the current year, and YYY is incremental beginning with 001and ending at 999 for the entire year.

8.3 Method Deviation

8.3.1 Not all deviations will result in an assay being invalid. The intent of the approval of the deviation is to determine whether the deviation irreparably compromised the product.

8.3.2 Sound scientific principles are used to disposition the results of assays where deviations occurred.

8.4 Method Modification

8.4.1 Method modifications require approval prior to their implementation.

8.4.2 Since method modifications are planned and have prior approval, method modifications should not result in compromising products.

8.4.3 Repeated modifications of the same nature to a given SOP may result in a change in method specifications for that particular document.

8.5 Blanket deviations and modifications can be written to cover multiple occurrences for the same event. Each data record should reference the same deviation or modification number.

8.6 Corrective action must be completed before deviations/modifications are closed.

8.7 Deviations to procedures must be documented using Attachment 1 (Method Deviation and Modification Form) and must be referenced by deviation numbers in the original data.

9.0 PROCEDURE

9.1 Method Deviation

9.1.1 The analyst/originator should obtain a deviation form and should document, if necessary, the nature of the deviation and the respective section of the SOP affected prior to consulting with the Pharmacist-in-charge.

9.1.1.1 The analyst should also note on the respective data sheets or attachments any ancillary information that would substantiate the disposition of the assay as being either valid or invalid.

9.1.1.2 Attach copies of supporting documentation to the original deviation form.

9.1.2 The Pharmacist-in-charge shall verify the deviation by reviewing data sheets and by discussing results with the analyst/originator. The analyst/originator will then obtain a deviation number from Quality and shall document the deviation number on the Method Deviation and Modification Form (Attachment 1).

9.1.3 If a deviation did not occur, the Pharmacist-in-charge will ensure that all data sheets or laboratory notebook entries accurately reflect the conduct of the assay.

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9.1.4 If a deviation is confirmed, the Pharmacist-in-charge must review the deviation form (Attachment 1) and conduct an assessment of the impact of the deviation.

9.1.4.1 The analyst/originator or Pharmacist-in-charge will enter the date, technician name, SOP number, a brief description of the requirement and the deviation, a description of why the deviation occurred and justification for why the deviation is acceptable.

(For example – If a sample were incubated at 5°C above process specifications for 3 hours, the deviation would state: "Product was incubated at 50°C for 3 hours. Procedure states the product must be incubated from 35°C – 45°C." State why the incubator went out of specification and document why the product is still viable or efficacious. Include any additional incubation needed to ensure viability.)

9.1.4.2 The objective of the assessment is to ascertain whether the deviation altered the sensitivity, specificity, accuracy or precision of the methodology being employed, where applicable, to an extent that it can no longer resolve the indicated limits of the quality parameter for which it is utilized. (i.e. has the qualification/validation status been affected?)

9.1.4.3 The Pharmacist-in-charge will review the documentation and discuss the deviation with appropriate personnel to determine the product disposition.

9.1.5 The Pharmacist-in-charge will determine whether the deviation warrants corrective action or if an investigation is needed, such as further training/retraining of the technician. The Pharmacist-in-charge will then schedule and document the training/retraining using approved training forms.

9.1.6 A Quality Control Officer shall review and sign the deviation form, approving the corrective action. The Pharmacist-in-charge and quality personnel must agree on due dates for the corrective action and/or investigation and will document the date(s) on Attachment 1. Unless justification is provided for otherwise, corrective actions and investigations should be completed within 30 days.

Note: If corrective action is required, the deviation is not closed until corrective action is complete.

9.1.7 The Pharmacist-in-charge will reschedule the testing or ancillary/extension testing if necessary, or dispositions the test as per the deviation form.

9.1.8 After signing the form, quality personnel will initial and date the deviation/modification log indicating that the item is complete.

9.2 Method Modification

9.2.1 Method modifications are planned changes to an established SOP.

9.2.2 Modifications to method specifications require approval prior to their implementation.

9.2.3 The technician proposing the planned change in SOP performance must notify the Pharmacist-in-charge.

9.2.4 When a modification is thought to be necessary, the Method Deviation and Modification Form (Attachment 1) must be completed and approved before the

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modified procedure can be performed. Discuss the duration of effectiveness of the modification (one lot only, one day, etc.). Determine whether the modification requires prior qualification/validation.

9.2.5 A Quality Control Officer shall review and sign the deviation form, approving the corrective action. The Pharmacist-in-charge and quality personnel must agree on due dates for the corrective action and will document the date(s) on Attachment 1. Unless justification is provided for otherwise, corrective actions and investigations should be completed within 30 days.

10.1 ATTACHMENTS

10.1 Attachment 1 – Method Deviation and Modification Form

10.2 Attachment 2 – Method Deviation Log Record

10.3 Attachment 3 – Method Modification Log Record

11.0 HISTORY

Version Number	Date Effective	Description of Change	Change Request Number
1.0	03/07/06	New SOP	CR06002
2.0	03-13-08	Delete Attachment #4, Minor changes and updates	CR07013

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METHOD DEVIATION AND MODIFICATION FORM

☐ Deviation (Unplanned) ☐ Modification (Planned)

Deviation/Modification Number: ____________________ Date: __________

SOP Number: ____________________ Technician: ____________________

Equipment ID: ____

Explain the procedural requirement: ____

____

____

Explain the deviation/modification (discuss root cause): ____________________

____

____

Qualification/Validation status affected? ☐ No ☐ Yes (explain)

____

____

Disposition: ☐ Dispose ☐ Rework ☐ Approve and Continue ☐ Results Valid ☐ Results Invalid

Justification for Disposition:

____

____

Investigation Required? ☐ No ☐ Yes, Due Date: __________

Corrective Action Required? ☐ No ☐ Yes, Due Date: __________

Recommended Corrective Action:

____

____

Corrective Action Performed By: ____________________ Date: __________

Recommended Preventative Action:

____

____

Preventative Action Performed By: ____________________ Date: __________

Prepared By: ____________________ Date: __________

Quality Review: ____________________ Date: __________

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METHOD DEVIATION LOG RECORD

Date	Originator	Deviation Number	SOP Number	Equipment ID	Brief Description	Corrective Action Required	Initial/Date
		D________ OOS? ☐				☐ Yes ☐ No	
		D________ OOS? ☐				☐ Yes ☐ No	
		D________ OOS? ☐				☐ Yes ☐ No	
		D________ OOS? ☐				☐ Yes ☐ No	
		D________ OOS? ☐				☐ Yes ☐ No	

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METHOD MODIFICATION LOG RECORD

Date	Originator	Modification Number	SOP Number	Equipment ID	Brief Description	Corrective Action Required	Initial/Date
		M________				☐ Yes ☐ No	
		M________				☐ Yes ☐ No	
		M________				☐ Yes ☐ No	
		M________				☐ Yes ☐ No	
		M________				☐ Yes ☐ No	

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TITLE: LOG OF MAINTENANCE AND CLEANING (L-MAC)	
SOP NUMBER: 1.040	**VERSION NUMBER: 4.0**
Non-Sterile and Sterile Laboratory	Effective Date 02-15-12
Originator: Annette Robinson	
Reviewer: Barry J Cadden	

1.0 PURPOSE

1.1 The purpose of this procedure is to describe the requirements for the log of maintenance and cleaning (L-MAC).

2.0 SCOPE

2.1 This procedure applies to all compounding personnel at New England Compounding Center (NECC).

3.0 RESPONSIBILITY

3.1 All personnel are responsible for ensuring that all maintenance procedures and cleaning performed are documented on the L-MAC.

4.0 REFERENCES

4.1 SOP 9.020 "Good Documentation Practices (GDP)"

5.0 DEFINITIONS

5.1 L-MAC – Log of Maintenance and Cleaning

6.0 FREQUENCY

6.2 During maintenance and cleaning activities

6.3 During service/out-of-service conditions on the equipment

7.0 EQUIPMENT & SUPPLIES

7.1 N/A

8.0 GENERAL INFORMATION

8.1 Malfunctions or other issues with the equipment are addressed and documented on the log of maintenance and cleaning (L-MAC).

8.2 Log of maintenance and cleaning (L-MAC) should not be removed from their designated area.

9.0 PROCEDURE

9.1 L-MACs should be located near their respective equipment to document timely entries.

9.2 Entries in the L-MAC shall be made at the time the activity occurred and in chronological order. Entries must include the date/initials and a written description of the activity being performed.

  9.2.1 Any routine/non-routine maintenance, cleaning or if the equipment is placed out-of-service shall be documented on the L-MAC.

9.3 If the equipment is moved from its location , and in the event there is subsequent work performed it shall be recorded on the L-MAC.

9.8 All entries made on the L-MAC must be in compliance with SOP 9.020, "Good Documentation Practices (GDP)".

9.9 Quality Control shall review L-MACs at least monthly.

LOG OF MAINTENANCE AND CLEANING (L-MAC)

Attachment 1

Equipment Description: ________________ Location: ____________ Month /Year: ____________

DATE	ACTIVITY	INITIALS

Quality Control: ______________________________

Reviewer: ______________________________

9.9.1 If possible, the review should be conducted where the L-MAC is located. L-MACs should not be removed from the area.

9.9.2 The Pharmacist-in-charge will sign and date the L-MAC certifying that the review was performed and any deficiencies encountered were corrected.

9.10 Equipment that requires monthly cleaning should have such cleaning documented on the L-MAC.

9.11 Entries shall be made on the L-MAC until the log is completed for the year. Completed L-MACs must be returned to Quality Control for subsequent archival in the Quality record files.

10.0 ATTACHMENTS

10.1 Attachment 1– Log of Maintenance and Cleaning (L-MAC)

11.0 HISTORY

Version Number	Date Effective	Description of Change	Change Request Number
1.0	NA	New SOP	CR06003
2.0	06/16/06	Change of LUMAC Attach 2 deleted 2 date columns	CR06064
3.0	11/05/07	More spaces on Attach1 and 2, Took out equip decript/ID #, time and checked by	CR07022
4.0	02-15-12	Took out Attachment 1, fixed minor grammar, took out 9.1-9.3 –changed LUMAC to L-MAC.	CR12001

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02-15-12

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TITLE: GENERAL NON-STERILE COMPOUNDING TECHNIQUE	
SOP NUMBER: 1.050	**VERSION NUMBER: 2.0**
Non-Sterile Laboratory	Effective Date 09/13/07
Originator:	
Reviewer:	

1.0 PURPOSE

1.1 The purpose of this procedure is to establish requirements for using proper technique when compounding.

2.0 SCOPE

2.1 This procedure applies to all compounding personnel at New England Compounding Center.

3.0 RESPONSIBILITY

3.1 The Pharmacist-in-charge shall supervise this procedure and document that all personnel responsible for compounding will comply with this procedure.

4.0 REFERENCES

4.1 USP Current Version <795> "Pharmaceutical Compounding – Non-Sterile Preparations".

4.2 SOP 9.120 "Required Garb for Non-Sterile Compounding Area".

5.0 DEFINITIONS

5.1 Technique – Methodology used in any area to minimize contamination of product.

5.2 Sanitizing Agents – 70% IPA, 2% bleach or sporicidin used to kill, inhibit growth of or physically remove microorganisms.

5.3 Compounding Area – Region in which microbial and particulate contamination is maintained within specified limits.

6.0 FREQUENCY

6.1 Daily when compounding activities are planned

7.0 EQUIPMENT & SUPPLIES

7.1 N/A

8.0 GENERAL INFORMATION

8.1 N/A

9.0 PROCEDURE

9.1 When working in the compounding laboratory:

- 9.1.1 Work surfaces should be sanitized before and after use.
- 9.1.2 Compounding equipment should be cleaned/sanitized as required.

9.2 When working in the compounding area, the following should be avoided:

- 9.2.1 Leaning over the work area and open containers.
- 9.2.2 Resting hands on the work area.

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9.2.3 Coughing over the work area.

9.2.4 Moving rapidly in the compounding area.

9.2.5 Eating, drinking, chewing gum, etc.

9.2.6 Performing any activities unrelated to compounding.

9.3 When working in the compounding area, the following should be performed:

9.3.1 Wearing appropriate apparel for the level of compounding to be performed.

9.3.2 Keeping work areas clutter-free.

9.3.3 Clean/sanitize work surfaces in between each compound.

9.3.4 Using slow, purposeful bodily movements.

9.3.5 Immediately wiping spills using appropriate cleaning/sanitizing procedures.

9.3.6 Immediately discarding any volatile or contaminated material.

9.3.7 Sanitizing gloves periodically during compounding and allowing sanitized gloves to air-dry before compounding. **Gloves should not be wet with 70% IPA while compounding because the sanitizing agent may contaminate the preparation.**

9.4 Personal Hygiene

9.4.1 Hair and exposed skin surfaces should be kept appropriately clean.

9.4.2 Hair should be completely covered by bouffant. Facial hair (beard/moustache) should be covered by a face mask.

9.4.3 Cosmetics and jewelry should be minimized in compounding area.

9.4.4 Personnel who have a potentially contagious disease or who have open wounds/lacerations should immediately contact the Pharmacist-in-charge/ Supervisor to determine if access to the compounding areas will be allowed.

10.0 ATTACHMENTS

10.1 N/A

11.0 HISTORY

Version Number	Date Effective	Description of Change	Change Request Number
1.0	03/07/06	New SOP	CR06004
2.0	09/13/07	SOP Changes	CR07004

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TITLE: GENERAL ASEPTIC TECHNIQUE	
SOP NUMBER: 1.060	**VERSION NUMBER: 3.0**
Sterile Laboratory	Effective Date 11-06-07
Originator:	
Reviewer: Bary J Cadd	

1.0 PURPOSE

1.1 The purpose of this procedure is to establish requirements for using aseptic technique in a clean room setting.

2.0 SCOPE

2.1 This procedure applies to all compounding personnel at New England Compounding Center who work in a clean room and are trained to produce sterile products (dosage forms).

3.0 RESPONSIBILITY

3.1 The Pharmacist-in-charge shall supervise this procedure and document that all personnel responsible for compounding will comply with this procedure.

4.0 REFERENCES

4.1 USP Current Version <795> "Pharmaceutical Compounding – Non-Sterile Preparations"

4.2 USP Current Version <797> "Pharmaceutical Compounding – Sterile Preparations"

4.3 SOP 9.090 "Required Garb for Clean Room Facility Access"

4.4 SOP 9.080 "Operation and Maintenance of MeriTech CleanTech 2000S Hand washers"

5.0 DEFINITIONS

5.1 Microbial Control – Produces a known state of microbial contamination

5.2 Aseptic Technique – Methodology used in any area to minimize contamination of microbes

5.3 Sterile Filling – Production process performed in the absence of microorganisms in an aseptic processing area (APA)

5.4 Bioburden – Number of microorganisms in the final product prior to sterilization

5.5 Disinfectant – (Sterile 70% Isopropyl Alcohol) used to kill, inhibit the growth of or physically remove microorganisms

5.6 Aseptic Area – Region in which microbial and particulate contamination is maintained within specified limits(Clean room and Glove box)

6.0 FREQUENCY

6.1 Daily when compounding activities are planned

7.0 EQUIPMENT & SUPPLIES

7.1 N/A

8.0 GENERAL INFORMATION

8.1 N/A

9.0 PROCEDURE

9.1 When working in the compounding laboratory:

9.1.1 Work surfaces should be disinfected before and after use.

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9.1.2 Compounding equipment and samples should be disinfected prior placement on the bench-top.

9.2 When working in an aseptic area, the following should be avoided:

9.2.1 Leaning over the work area and open containers.

9.2.2 Resting hands on the work area.

9.2.3 Coughing over the work area.

9.2.4 Moving rapidly in the compounding area.

9.2.5 Using a glove box as a storage space when not in use.

9.2.6 Eating, drinking, chewing gum, etc.

9.2.7 Storing food, drinks or personal items in the aseptic area.

9.2.8 Performing any activities unrelated to compounding.

9.3 When working in an aseptic area, the following should be performed:

9.3.1 Wearing appropriate clean room apparel for the level of sterile compounding to be performed.

9.3.2 Disinfecting glove boxes, sampling equipment and bench-tops prior to use.

9.3.3 Keeping work areas clutter-free.

9.3.4 Disinfecting work surfaces in between compounding of batches/samples.

9.3.5 Limiting arm movement in glove boxes.

9.3.6 Using slow, purposeful bodily movements.

9.3.7 Immediately wiping spills using appropriate disinfecting procedures.

9.3.8 Immediately discarding any biohazard or contaminated material.

9.3.9 When working with a sterile container with a cap/lid, placing the cap/lid on its side or top if it must be laid on the work surface.

9.4 When working in a glove box, the following should be performed:

9.4.1 Personnel should wash their hands prior to entering the clean room facility and when re-entering the sterile compounding area.

9.4.2 Appropriate gowning suitable for sterile compounding should be worn. Anyone working in the glove box must put on booties, bouffant, facemask, coveralls or a full-length frock and gloves.

9.4.3 The glove box blower should be operating continually, 24 hours a day. If this is not possible, the glove box should be turned on at least 30 minutes prior to use.

9.4.4 The interior work surface and sides should be cleaned with a suitable disinfectant prior to and after each use. Avoid spraying or squirting solutions onto the HEPA filter.

9.4.5 Any bottles, vials, or containers should be wiped down with sterile 70% IPA prior to placement in the glove box to prevent possible contamination.

9.4.5.1 Gloves should be sprayed with sterile 70% IPA periodically during compounding. Allow disinfected gloves to air-dry before handling samples or instruments.

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Gloves should not be wet with sterile 70% IPA while compounding because the sterile 70% IPA may contaminate the preparation.

9.5 Aseptic Technique in the Glove Box

9.5.1 Only one formulation type shall be compounded at one time in a specified compounding area.

9.5.2 Outer pouches and wraps should be removed prior to placement in the antechamber.

9.5.3 Objects placed in the glove box should be positioned to allow sufficient airflow with minimal obstruction. A direct path must be maintained between the filter and the area inside the glove box where manipulations are being performed.

9.5.4 Always minimize clutter.

9.5.5 Waste and other items unrelated to compounding should never enter the glove box.

9.5.6 Disinfect gloves periodically. Glove cleanliness is reduced each time non-sterile items are handled

9.6 Syringes and Needles

9.6.1 Commercially sterilized, disposable, and latex-free syringes with a locking mechanism for needles shall be used to compound sterile preparations.

9.6.2 To maximize accuracy, the smallest syringe that can hold a desired amount of solution shall be used.

9.6.3 To maintain sterility, two parts of the syringe shall never be touched: (1) the tip and (2) the plunger.

9.6.4 After proper sanitizing of the exterior package of the syringe, the syringe shall be removed from the protective syringe package in the glove box.

9.6.5 The exterior package shall be discarded appropriately and shall not be placed on any surface within the glove box.

9.6.6 Needles shall be selected and opened following the same procedure for selecting/opening syringes.

9.6.7 To maintain sterility, two parts of the needle shall never be touched or swabbed with alcohol: (1) the hub and (2) the shaft.

9.6.8 Before inserting a needle into a vial/bag, the injection site must be wiped with sterile 70% isopropyl alcohol using an alcohol swab or a low-lint wipe. Make sure to wipe in one direction to sterilize the port and to reduce particulate matter.

9.6.9 Used syringes and needles shall be placed in an appropriate medical sharps container. Once the medical sharps container has reached the maximum fill limit, it shall be sealed appropriately and discarded with a contracted medical waste company.

9.7 Personal Hygiene

9.7.1 Hair and exposed skin surfaces should be kept appropriately clean.

9.7.2 Hair should be completely covered by bouffant. Facial hair (beard/mustache) should be covered by a face mask.

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9.7.3 No cosmetics should be worn and jewelry should not be exposed in controlled areas such as the clean room.

9.7.4 Personnel who have a potentially contagious disease or who have open wounds/lacerations should immediately contact the Pharmacist-in-charge to determine if access to controlled areas will be allowed.

9.8 Sterile Equipment and Materials

9.8.1 Check the expiration dates when using autoclaved equipment.

9.8.2 Ensure the color indicator (if applicable) has changed to the proper color indicating sterilization has occurred.

9.8.3 When removing the autoclave wrapping, handle the material with gloved hands and with minimal manipulations.

10 ATTACHMENTS

10.7 N/A

11 HISTORY

Version Number	Date Effective	Description of Change	Change Request Number
1.0	03-07-06	New SOP	CR06005
2.0	03/30/06	Changed all references to hoods/LAFWs to glove box. Added section 9.5.1.	CR06059
3.0	11-06-07	Deleted 9.8, Minor updates and changes	CR07019

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6 A

TITLE: EMPLOYEE ORIENTATION /TRAINING	
SOP NUMBER: 2.010	**VERSION NUMBER: 2.0**
Non-Sterile and Sterile Laboratory	Effective Date: 11/06/07
Originator:	
Reviewer:	:

1.0 PURPOSE

1.1 This procedure defines the requirements for new employee orientation and provides a standard method for training.

2.0 SCOPE

2.1 This procedure applies to all employees training at New England Compounding Center and includes, but is not limited to, compounding training, procedural training and professional development.

3.0 RESPONSIBILITY

3.1 It is the responsibility of the Pharmacist-in-charge to ensure that each employee is properly trained, by providing initial training or assigning a qualified employer to perform orientation training and provide the time for employees to remain current with their training.

3.2 Training files shall be maintained by the Pharmacist-in-charge or by Quality Control.

4.0 REFERENCES

4.1 SOP 1.010 "Policies and Procedures"

4.2 SOP 2.020 "Compounding Personnel Orientation Program"

4.3 SOP 2.030 "Sterile Compounding Personnel Qualification"

4.4 SOP 2.040 "Non-Sterile Compounding Personnel Qualification"

5.0 DEFINITIONS

5.1 N/A

6.0 FREQUENCY

6.1 Commencement of employment

6.2 Before performing a new procedure

7.0 EQUIPMENT & SUPPLIES

7.1 N/A

8.0 GENERAL INFORMATION

8.1 Documentation

8.1.1 If group training is conducted, details of the training session should be provided in the individual employee files. The original training record is filed in the folder of the first trainee on the list, and copies of the training record are placed in the folders of each subsequent trainee on the list.

8.1.2 Job Qualification Records/Resumes are completed as documented evidence that the employee is qualified to perform his/her function.

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8.2 The Ongoing Employee Training (Attachment 1) is completed and filed whenever an employee participates in any training activity.

8.3 Only qualified personnel may administer training.

9.0 PROCEDURE

9.1 Personnel will go through new employee orientation upon employment at New England Compounding Center (refer to SOP 2.020, "Compounding Personnel Orientation Program").

9.2 Designee will review the organizational chart, quality policy, work and lunch hours, employee benefits and company policies.

9.3 The Pharmacist-in-charge or other qualified personnel will review specific job performance objectives and job descriptions, give staff introductions and provide a building tour, workspace, keys, and any necessary supplies. The Pharmacist-in-charge or other qualified personnel will also discuss performance review and facilities issues and will review training requirements.

9.4 For specific task training, the employee will observe the test being performed (where applicable) and will then perform the test under direct supervision. Where appropriate, training checklists will be used to document the training and indicate that the employee is able to complete the tasks independently.

9.5 Additional training or re-training may be necessary for any one of the following reasons: employment development, new technology or equipment, changed position or position requirements or an employee does not meet the requirements of the current position.

9.5.1 The Pharmacist-in-charge is responsible for determining and/or pre-approving specific training needs of each employee on a periodic basis.

9.5.2 All additional training that is not considered continuing education training will be documented on the Employee Training Record (Attachment 1) whenever the employee participates in any of the following training activities:

9.5.2.1 Formal Coursework

9.5.2.2 Seminars

9.5.2.3 Workshops

9.5.2.4 Internal New England Compounding Center courses

9.5.3 A certificate from an outside training course or seminar may take the place of the Employee Training Record. If no certificate was presented, complete Attachment 1, reference the course material in the "Description of Training" section and retain a copy of the course for reference.

9.6 Employees must receive annual training on quality systems. It is the responsibility of the Pharmacists, Supervisor and/or Quality Control to schedule, perform and document annual training.

9.6.1 New and updated procedure training is covered in the SOP 1.010, "Policies and Procedures."

9.7 Personnel training files shall be maintained by the Pharmacist-in-charge or by the Quality Control Officer.

10.0 ATTACHMENTS

10.1 Attachment 1 – Ongoing Employee Training

1-06-07

11.0 HISTORY

Version Number	Date Effective	Description of Change	Change Request Number
1.0	03/08/06	New SOP	CR06006
2.0	11/06/07	Minor changes and updates	CR07008

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pmk
11-06-0

ONGOING EMPLOYEE TRAINING

Attachment 1

Date: ____________________

Training Topic: ____________________

Trainer Signature: ____________________

Trainee Name (Printed)	Trainee Name (Signature)	Date

Description of Training: ____________________

____

____

____

Reviewed By: ____________________ **Date:** ____________________

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TITLE: COMPOUNDING PERSONNEL ORIENTATION PROGRAM	
SOP NUMBER: 2.020	**VERSION NUMBER: 3.0**
Sterile and Non-Sterile Laboratory	Effective Date: 07-11-07
Originator:	
Reviewer:	

1.0 PURPOSE

1.1 New England Compounding Center shall require job orientation training for all compounding personnel to ensure that all personnel understand their responsibilities with regard to compounding.

2.0 SCOPE

2.1 This procedure applies to all compounding personnel at New England Compounding Center.

3.0 RESPONSIBILITY

3.1 The Pharmacist-in-charge shall supervise this procedure or document that another staff member has been designated to complete this task.

4.0 REFERENCES

4.1 SOP 1.010 "Policies and Procedures"

4.2 SOP 2.030 "Sterile Compounding Personnel Qualification"

4.3 SOP 2.040 "Non-Sterile Compounding Personnel Qualification"

5.0 DEFINITIONS

5.1 N/A

6.0 FREQUENCY

6.1 Commencement of employment

6.2 Upon assignment to another position or compounding responsibility

7.0 EQUIPMENT & SUPPLIES

7.1 N/A

8.0 GENERAL INFORMATION

8.1 All training must be documented and placed in the employee's training folder, kept in Human Resources.

8.2 The Pharmacist-in-charge must be qualified and capable of training appropriate staff in the implementation of new or revised SOPs (refer to SOP 1.010, "Policies and Procedures").

9.0 PROCEDURE

9.1 All personnel shall complete the job orientation program.

9.2 A Job Description shall be made available to all compounding personnel. The Job Description will detail job activities, responsibilities, qualifications and requirements for the position.

  9.2.1 The employee must read and understand the job description and must sign the job description to acknowledge comprehension.

  9.2.2 A member of management must also sign the job description.

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9.3 Personnel shall complete the Orientation Checklist (Attachment 1) before assuming all responsibilities of the position. The Orientation Checklist should include, but not be limited to, the following items:

- 9.3.1 Pre-Hire
  - 9.3.1.1 First Interview
  - 9.3.1.2 Second Interview
  - 9.3.1.3 Application for Employment
  - 9.3.1.4 Confidentiality Form
  - 9.3.1.5 Resume
  - 9.3.1.6 References
- 9.3.2 Upon Hire
  - 9.3.2.1 Employment Agreement
  - 9.3.2.2 I-9 Employment Eligibility Verification
  - 9.3.2.3 W-4 Employee's Withholding Allowance Certificate
  - 9.3.2.4 M-4 MA Employee's Withholding Allowance Certificate
  - 9.3.2.5 Review Employee Handbook
- 9.3.3 Health Plan Election/ Sign up (after 30 days)
- 9.3.4 401K / Sign up (after 12 months)

9.4 An employee file shall be maintained for all compounding personnel. The portfolio shall contain, but not be limited to, the following items, which will be kept in Human Resources:

- 9.4.1 Resume
- 9.4.2 Appropriate Orientation Checklist
- 9.4.3 Incident reports or complaints specific to a compounder (if applicable)
- 9.4.4 Employee performance evaluation reports (if applicable)

9.5 New England Compounding Center shall keep all items in personnel files confidential.

10.0 ATTACHMENTS

10.1 Attachment 1 – Compounding Personnel Orientation Program Checklist

11.0 HISTORY

Version Number	Date Effective	Description of Change	Change Request Number
1.0	03-08-06	New SOP	CR06007
2.0	05-01-06	Attachment redone and Orientation Requirements revamped for NECC.	NA
3.0	07-11-07	Annual Review and minor text changes	CR07001

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07-11-07

ORIENTATION CHECKLIST – COMPOUNDING PERSONNEL

Attachment 1

The Compounding Support Personnel shall be oriented to the pharmacy and the responsibilities and tasks of the position.

Pre-Hire	**Date Completed**
First Interview Date	________________
Second Interview Date	________________
Application for Employment	________________
Confidentiality Form	________________
Resume	________________
References	________________

Upon Hire	**Date Completed**
Employment Agreement	________________
I-9 Employment Eligibility Verification	________________
W-4 Employee's Withholding Allowance Certificate	________________
M-4 MA Employee's Withholding Allowance Certificate	________________
Health Plan Election/Sign-up	________________
401K	________________

Training	**Date Completed**
Review Employee Handbook	________________

Employee Name____Date____________

Employee Signature_____________________________________Date____________

Trainer Signature______________________________________Date____________

ORIGINAL
07-11-07

TITLE: STERILE COMPOUNDING PERSONNEL QUALIFICATIONS/TRAINING

SOP NUMBER: 2.030 **VERSION NUMBER: 3.0**

Sterile Laboratory Current Effective Date 02/28/08

Originator:

Reviewer: Barry

1.0 PURPOSE

1.1 New England Compounding Center shall require basic qualifications for each employee active in the process of sterile compounding.

2.0 SCOPE

2.1 This procedure applies to all sterile compounding personnel at New England Compounding Center.

3.0 RESPONSIBILITY

3.1 The Pharmacist-in-charge shall supervise this procedure or document that another staff member has been designated to complete this task.

3.1 Each pharmacist shall be responsible for ensuring his or her professional license is kept current and in good standing.

4.0 REFERENCES

4.1 All licensure certificates

4.2 All sterile compounding training course certificates

4.3 SOP 9.100 "Sterile Compounding Process Validation (Media Fills)"

5.0 DEFINITIONS

5.1 N/A

6.0 FREQUENCY

6.1 Commencement of employment

6.2 Policy reviewed annually

7.0 EQUIPMENT & SUPPLIES

7.1 N/A

8.0 GENERAL INFORMATION

8.1 N/A

9.0 PROCEDURE

9.1 Pharmacist

9.1.1 Each pharmacist must provide documentation of a current license in good standing with the Mass State Board of Pharmacy.

9.1.2 Each pharmacist must operate according to the Mass State Board of Pharmacy – Pharmacy Practice Rules and Regulations.

9.1.3 Each pharmacist will be responsible for obtaining the appropriate number of continuing education hours, for licensure, as required by the Mass State Board of Pharmacy – Pharmacy Practice Rules and Regulations.

9.1.3.1 Each pharmacist involved in the process of sterile compounding will be required to annually obtain no less than five hours of continuing

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education directly related to sterile compounding, when available. Hours earned may be applied to the continuing education hours required by the Mass State Board of Pharmacy.

9.1.1.1 All licensed professionals are required to display their licensure certificates in the pharmacy area for easy access to regulatory agents and the public.

9.1.1.2 All licensed professionals shall display any additional information required by the Mass State Board of Pharmacy.

9.1.2 Each pharmacist must be able to make clinical and compounding formulation decisions.

9.2 Personnel involved in the sterile compounding process will be evaluated on his or her physical ability to perform the assigned compounding responsibility without compromising the integrity of the compound. This will include handicap issues (along with dexterity skills) and any illness or injury.

9.3 If necessary, support personnel will be trained on his or her specific duties involving the sterile compounding process.

9.4 All sterile compounding personnel shall undergo training and validation of sterile compounding.

9.4.1 Each employee shall view and understand the Video Training Program Technique/DVD, "Getting Started in Aseptic Compounding".

9.4.2 Each new clean room employee (RPh, sterile tech) shall complete the "Aseptic Training Program Check List" in a reasonable time frame. Each item on the "Aseptic Training Program Check List" (Attachment 2) shall be initialed by the instructing pharmacist once trainee exhibits satisfactory understanding/competency in the theory/practice of each skill set.

9.4.3 Each employee shall be evaluated on his or her designated aseptic process a minimum of every 6 months for high-risk preparations. A validation test shall also be required whenever the quality assurance program yields an unacceptable result or unacceptable techniques are observed. (Attachment 1)

9.4.4 Should an employee or procedure fail an evaluation test, he or she will be restricted from performing the task until an evaluation test is passed.

9.4.5 The Pharmacist-in-charge shall be responsible for determining if the employee or procedure requires testing more frequently than semi-annually.

9.4.6 Documentation of the evaluation and verification process shall be documented and retained appropriately in the designated employee portfolio.

9.4.7 All sterile compounding personnel must successfully complete three sterile compounding process validations according to SOP 9.100, "Sterile Compounding Process Validation (Media Fills)" before he or she can prepare parenterals.

10.0 ATTACHMENTS

10.1 Attachment 1 – Media Fill Validation of Sterile Compounding

10.2 Attachment 2 – Aseptic Training Program Check List

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11.0 HISTORY

Version Number	Date Effective	Description of Change	Change Request Number
1.0	03-08-06	New SOP	CR06008
2.0	11-06-07	Changes and Revisions	CR07007
3.0	02-28-08	Changes to Attachment 1,added Attachment 2 the Aseptic training program List	CR08003

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MEDIA FILL VALIDATION of STERILE COMPOUNDING

Attachment 1

Date: ____________________ Operator: ____

Control (A) 3 DAY + / -	**Control (B) 7 DAY + / -**	**Control (C) 14 DAY + / -**
Sample 1 + / -	Sample 1 + / -	Sample 1 + / -
Sample 2 + / -	Sample 2 + / -	Sample 2 + / -
Sample 3 + / -	Sample 3 + / -	Sample 3 + / -

NUMBER OF UNITS	
TYPE OF CONTAINER	
SIZE	
FILL VOLUME	
SOYBEAN CASEIN	
TSB AGAR PLATE	

Touch Plate (1) + Control	☐ Pass	☐ Fail *	Touch Plate (3)	☐ Pass	☐ Fail *
Touch Plate (2) - Control	☐ Pass	☐ Fail *	Touch Plate (4)	☐ Pass	☐ Fail *

Media Fill: ☐ Pass ☐ Fail

*CFU (acceptable) = 1

Comments: ____
____
____

Performed By: ____________________________________ Date: ______________

Reviewed By: ____________________________________ **Date:** ______________

ORIGINAL

02-28-08

TITLE: NON-STERILE COMPOUNDING PERSONNEL QUALIFICATION	
SOP NUMBER: 2.040	**VERSION NUMBER: 3.0**
Non-Sterile Laboratory	Effective Date 03/15/12
Originator:	
Reviewer:	

1.0 PURPOSE

1.1 New England Compounding Center shall require basic qualifications for each employee active in the process of non-sterile compounding.

2.0 SCOPE

2.1 This procedure applies to all non-sterile compounding personnel at New England Compounding Center.

3.0 RESPONSIBILITY

3.1 The Pharmacist-in-charge shall supervise this procedure or document that another staff member has been designated to complete this task.

3.2 Each pharmacist shall be responsible for ensuring his or her professional license is current and in good standing.

3.3 Each pharmacy technician shall be responsible for ensuring his or her state registration and national certification is current and in good standing.

4.0 REFERENCES

4.1 All licensure certificates

5.0 DEFINITIONS

5.1 N/A

6.0 FREQUENCY

6.1 Commencement of employment

6.2 Policy reviewed annually

7.0 EQUIPMENT & SUPPLIES

7.1 N/A

8.0 GENERAL INFORMATION

8.1 N/A

9.0 PROCEDURE

9.1 Pharmacist

9.1.1 Each pharmacist must provide documentation of a current license in good standing with the Mass State Board of Pharmacy.

9.1.2 Each pharmacist must operate according to the Mass State Board of Pharmacy – Pharmacy Practice Rules and Regulations.

9.1.3 Each pharmacist will be responsible for obtaining the appropriate number of continuing education hours, for licensure, as required by the Mass State Board of Pharmacy – Pharmacy Practice Rules and Regulations.

9.1.3.1 All licensed professionals are required to make copies and provide current certificates.

9.1.4 All licensed professionals shall make copies and provide any additional information required by the Mass State Board of Pharmacy. These will be located in the Quality Control area.

9.2 Technician

9.2.1 Each technician that has completed 500 hours of employment must register with the Mass State Board of Pharmacy.

9.2.2 Each technician must operate according to the Mass State Board of Pharmacy 247 CMR 8.02.

9.2.3 After one year employment, technicians are required to become Nationally Certified.

9.2.4 All certified technicians shall make copies of their certificates. These will be kept in personal folders in the Quality Control area for regulatory agents, upon request.

9.3 Personnel involved in the non-sterile compounding process will be evaluated on his or her physical ability to perform the assigned compounding responsibility without compromising the integrity of the compound. This will include handicap issues (along with appropriate dexterity skills) and any illness or injury.

9.4 Support personnel will be trained on his or her specific duties involving the non-sterile compounding process.

9.5 Non-Sterile Compounding personnel should be familiar with basic compounded preparations of:

9.5.1.1 Non-Sterile Required Garb - Attachment 1
9.5.1.2 Analytical Balance - Attachment 2
9.5.1.3 Solutions - Attachment 3
9.5.1.4 Acid/Base Solutions - Attachment 4
9.5.1.5 Suspensions - Attachment 5
9.5.1.6 Transdermal Creams - Attachment 6
9.5.1.7 Transdermal Pluronic Gel - Attachment 7
9.5.1.8 Capsules - Attachment 8
9.5.1.9 Suppositories - Attachment 9
9.5.1.10 Milling - Attachment 10

9.6 Complex compound formulations shall require additional training as determined by the Pharmacist-in-charge.

9.7 All non-sterile compounding personnel shall undergo training and validation of non-sterile compounding.

9.7.1 Each employee shall be evaluated on his or her designated process annually. A validation test shall also be required whenever the quality assurance program yields an unacceptable result or unacceptable techniques are observed.

9.7.2 Should an employee or procedure fail an evaluation test, he or she will be restricted from performing the task until an evaluation test is passed.

9.7.3 The Supervisor/Pharmacist-in-charge shall be responsible for determining if the employee or procedure requires testing more frequently than annually.

9.7.4 Documentation of the evaluation and verification process shall be documented and retained appropriately in technician qualification binder.

10.0 ATTACHMENTS

10.1 N/A

11.0 HISTORY

Version Number	Date Effective	Description of Change	Change Request Number
1.0	N/A	New SOP	CR06009
2.0	11-08-07	Deleted 9.1.3.1, Attachments not attached anymore, Added responsibilities of Technicians	CR07021
3.0	03-15-12	Updates, Keep up with changes and training	CR12003

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RPh/Technician Training Record

Attachment 1

Competency: Non-Sterile Required Garb

Trainee: ______________________________

Trainer: ______________________________ Date: ____________________

Procedure	Observation Dates/Initials of trainer*			Demonstration while under observation (Dates/Initials of trainer)**						
1. Explain required garb & importance of dressing order										
- Hair net										
- Face mask										
- Goggles										
- Frock, Disposable gown										
- Gloves										
2. Explain what you should do with garb when:										
- Need to leave lab area for any reason										
3. Explain when one needs to garb-up in the non-sterile lab										

* Trainee is required to observe at least twice. Additional observation may be necessary, as some trainee's have different levels of experience.

** Trainee is required to be observed at least twice. Additional demonstration may be necessary, as some trainee's have different levels of experience.

By signing below you agree that you fully understand the process detailed above:

Trainee: ______________________________ Date: ____________

By signing below you agree that you feel the technician is fully trained and proficient at performing the process detailed above:

Trainer: ______________________________ Date: ____________

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03-15-12

TITLE: NON-STERILE COMPOUNDING PERSONNEL QUALIFICATION

SOP NUMBER: 2.040 **VERSION NUMBER: 3.0**

RPh/Technician Competency Record

Attachment 1

Competency: Non-Sterile Required Garb

Trainee: ____________________

Qualifier: ____________________ Date: ____________

Procedure	Qualify		Additional Comments
	Yes	No	
1. Explain required garb & importance of dressing order			
• Hair net			
• Face mask			
• Goggles			
• Frock, Disposable gown			
• Gloves			
2. Explain what you should do with garb when:			
• Need to leave lab area for any reason			
3. Explain when one needs to garb-up in the non-sterile lab			

By signing below you agree that you fully understand the process detailed above:

Trainee: ____________________ Date: __________

By signing below you agree that you feel the technician is fully trained and proficient at performing the process detailed above:

Qualifier: ____________________ Date: __________

RPh/Technician Training Record

Attachment 2

Competency: Analytical Balance
Trainee: ______________________
Trainer: ______________________ Date: ______________

Procedure	**Observation Dates/Initials of trainer***			**Demonstration while under observation (Dates/Initials of trainer)****						
1. Explain the different buttons on the scale (i.e.-power supply, tare, print)										
2. Demonstrate how to tare the scale										
3. Explain why it is important to tare the scale										
4. Explain the accuracy of each scale - minimum and maximum weight										
• Scale in Flow Hood 210g										
• Scale in Flow Hood 610g										
• Top Loader in Fume Hood										
5. Weigh at least 3 ingredients										
• Explain the order of which ingredients should be weighed										
6. Print-out weights										
7. Properly attach and sign on the log sheet										
8. Clean up										

* Trainee is required to observe at least twice. Additional observation may be necessary, as some trainee's have different levels of experience.

** Trainee is required to be observed at least twice. Additional demonstration may be necessary, as some trainee's have different levels of experience.

By signing below you agree that you fully understand the process detailed above:
Trainee: ______________________ Date: __________

By signing below you agree that you feel the technician is fully trained and proficient at performing the process detailed above:
Trainer: ______________________ Date: __________

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RPh/Technician Competency Record

Attachment 2

Competency: Analytical Balance
Trainee: ______________________
Qualifier: ______________________ Date: ______________

Procedure	Qualify		Additional Comments
	Yes	No	
1. Explain the different buttons on the scale (i.e.-power supply, tare, print)			
2. Demonstrate how to tare the scale			
3. Explain why is it important to tare the scale			
4. Explain the accuracy of each scale - minimum and maximum weight			
• Scale in Flow Hood 210g			
• Scale in Flow Hood 610g			
• Top Loader in Fume Hood			
5. Weigh at least 3 ingredients			
• Explain the order of which ingredients should be weighed			
6. Print-out weights			
7. Properly attach and sign on the log sheet			
8. Clean up			

By signing below you agree that you fully understand the process detailed above:
Trainee: ______________________ Date: __________

By signing below you agree that you feel the technician is fully trained and proficient at performing the process detailed above:
Qualifier: ______________________ Date: __________

RPh/Technician Training Record

Attachment 3

Competency: Solutions
Trainee: ____________________
Trainer: ____________________ Date: ____________________

Procedure	**Observation Dates/Initials of trainer***			**Demonstration while under observation (Dates/Initials of trainer)****						
1. Calculations										
2. Add powders to solution										
3. Qs to final volume										
4. Place a mark - a - dose strip on an oral syringe										
5. Select the correct - sized adapt -a - cap										
6. Clean up										

* Trainee is required to observe at least twice. Additional observation may be necessary, as some trainee's have different levels of experience.

** Trainee is required to be observed at least twice. Additional demonstration may be necessary, as some trainee's have different levels of experience.

By signing below you agree that you fully understand the process detailed above:
Trainee: ____________________ Date: __________

By signing below you agree that you feel the technician is fully trained and proficient at performing the process detailed above:
Trainer: ____________________ Date: __________

03-15-12

RPh/Technician Competency Record

Attachment 3

Competency: Solutions
Trainee: ____________________
Qualifier: ____________________ Date: ____________

Procedure	Qualify		Additional Comments
	Yes	No	
1. Calculations			
2. Add powders to solution			
3. Qs to final volume			
4. Place a mark - a - dose strip on an oral syringe			
5. Select the correct - sized adapt -a -cap			
6. Clean up			

By signing below you agree that you fully understand the process detailed above:
Trainee: ____________________ Date: __________

By signing below you agree that you feel the technician is competent performing the process detailed above:
Qualifier: ____________________ Date: __________

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RPh/Technician Training Record

Attachment 4

Competency: Acid/Base Solutions
Trainee: ____________________________
Trainer: ____________________________ Date: __________________

Procedure	Observation Dates/Initials of trainer*			Demonstration while under observation (Dates/Initials of trainer)**						
1. Calculations										
2. Explain required protective garb/equipment when working with acids										
3. Explain where caustics are stored										
4. Make solution										
• Explain sequence of adding ingredients for an acid solution										
5. Spill Kit										
• Show where spill kit is located in lab										
• Explain how to use the spill kit										
6. Explain the type of container that most acid solutions are dispensed										
7. Proper disposal of acid solutions										
8. Clean up										

* Trainee is required to observe at least twice. Additional observation may be necessary, as some trainee's have different levels of experience.

** Trainee is required to be observed at least twice. Additional demonstration may be necessary, as some trainee's have different levels of experience.

By signing below you agree that you fully understand the process detailed above:
Trainee: ____________________________ Date: ___________

By signing below you agree that you feel the technician is fully trained and proficient at performing the process detailed above:
Trainer: ____________________________ Date: ___________

TITLE: NON-STERILE COMPOUNDING PERSONNEL QUALIFICATION

SOP NUMBER: 2.040 **VERSION NUMBER: 3.0**

RPh/Technician Competency Record

Attachment 4

Competency: Acid/Base Solutions
Trainee: ____________________
Qualifier: ____________________ Date ____________

Procedure	Quality		Additional Comments
	Yes	No	
1. Calculations			
2. Explain required protective garb/equipment when working with acids			
3. Explain where caustics are stored			
4. Make solution			
• Explain sequence of adding ingredients for an acid solution			
5. Spill Kit			
• Show where spill kit is located in lab			
• Explain how to use the spill kit			
6. Explain the type of container that most acid solutions are dispensed			
7. Proper disposal of acid solutions			
8. Clean up			

By signing below you agree that you fully understand the process detailed above:
Trainee: ____________________ Date: __________

By signing below you agree that you feel the technician is competent performing the process detailed above:
Qualifier: ____________________ Date: __________

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RPh/Technician Training Record

Attachment 5

Competency: Suspensions
Trainee: ______________________
Trainer: ______________________ Date: ______________

Procedure	**Observation Dates/Initials of trainer***			**Demonstration while under observation (Dates/Initials of trainer)****						
1. Calculations										
2. Mix ingredients in a mortar & pestle										
3. Wet powders										
• Explain purpose of wetting powders.										
• State 3 examples of a wetting agent.										
• Explain purpose of silica										
• Explain necessary precautions when using silica										
4. Add suspension base to mortar & pestle										
5. Wash mortar										
5. Qs to final volume										
6. Place a mark-a-dose strip on an oral syringe										
7. Select the correct-sized adapt-a-cap										
8. Clean up										

* Trainee is required to observe at least twice. Additional observation may be necessary, as some trainee's have different levels of experience.

** Trainee is required to be observed at least twice. Additional demonstration may be necessary, as some trainee's have different levels of experience.

By signing below you agree that you fully understand the process detailed above:
Trainee: ______________________ Date: __________

By signing below you agree that you feel the technician is fully trained and proficient at performing the process detailed above:
Trainer: ______________________ Date: __________

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RPh/Technician Competency Record
Attachment 5

Competency: Suspensions
Trainee: ____________________
Qualifier: ____________________ Date: ____________

Procedure	Qualify		Additional Comments
	Yes	No	
1. Calculations			
2. Mix ingredients in a mortar & pestle			
3. Wet powders			
• Explain purpose of wetting powders.			
• State 3 examples of a wetting agent.			
• Explain purpose of silica			
• Explain necessary precautions when using silica			
4. Add suspension base to mortar & pestle			
5. Wash mortar			
5. Qs to final volume			
6. Place a mark-a-dose strip on an oral syringe			
7. Select the correct-sized adapt-a-cap			
8. Clean up			

By signing below you agree that you fully understand the process detailed above:
Trainee: ____________________ Date: ____________

By signing below you agree that you feel the technician is competent performing the process detailed above:
Qualifier: ____________________ Date: ____________

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RPh/Technician Training Record
Attachment 6

Competency: Transdermal Cream
Trainee: ____________________
Trainer: ____________________ Date: ____________

Procedure	**Observation Dates/Initials of trainer***			**Demonstration while under observation (Dates/Initials of trainer)****						
1. Calculations										
2. Wetting powders										
• State 3 wetting agents										
3. qs to final volume										
• Explain what qs means										
• Show how to calculate amount of cream needed										
4. Mix well										

* Trainee is required to observe at least twice. Additional observation may be necessary, as some trainee's have different levels of experience.

** Trainee is required to be observed at least twice. Additional demonstration may be necessary, as some trainee's have different levels of experience.

By signing below you agree that you fully understand the process detailed above:
Trainee: ____________________ Date: __________

By signing below you agree that you feel the technician is fully trained and proficient at performing the process detailed above:
Trainer: ____________________ Date: __________

RPh/Technician Competency Record

Attachment 6

Competency: Transdermal Cream
Trainee: ______________________
Qualifier: ______________________ Date: ______________

Procedure	Qualify		Additional Comments
	Yes	No	
1. Calculations			
2. Wetting powders			
- State 3 wetting agents			
3. qs to final volume			
- Explain what qs means			
- Show how to calculate amount of cream needed			
4. Mix well			

By signing below you agree that you fully understand the process detailed above:
Trainee: ____________________________ Date: __________

By signing below you agree that you feel the technician is fully competent at performing the process detailed above:
Qualifier: ____________________________ Date: __________

RPh/Technician Training Record

Attachment 7

Competency: Transdermal Pluronic Gel
Trainee: ______________________
Trainer: ______________________ Date: ______________

Procedure	**Observation Dates/Initials of trainer***			**Demonstration while under observation (Dates/Initials of trainer)****						
1. Calculations										
2. Wetting powders										
• State 3 wetting agents										
3. Add lecithin phase										
• Explain how much lecithin phase is added to each 30gm										
4. qs with pluronic gel										
• Explain what qs means.										
5. Explain why pluronic gel is stored in the refrigerator										

* Trainee is required to observe at least twice. Additional observation may be necessary, as some trainee's have different levels of experience.

** Trainee is required to be observed at least twice. Additional demonstration may be necessary, as some trainee's have different levels of experience.

By signing below you agree that you fully understand the process detailed above:
Trainee: ______________________ Date: __________

By signing below you agree that you feel the technician is fully trained and proficient at performing the process detailed above:
Trainer: ______________________ Date: __________

RPh/Technician Competency Record

Attachment 7

Competency: Transdermal Pluronic Gel
Trainee: ____________________
Qualifier: ____________________ Date: ______________

Procedure	Qualify		Additional Comments
	Yes	No	
1. Calculations			
2. Wetting powders			
• State 3 wetting agents			
3. Add lecithin phase			
• Explain how much lecithin phase is added to each 30gm			
4. qs with pluronic gel			
• Explain what qs means.			
5. Explain why pluronic gel is stored in the refrigerator			

By signing below you agree that you fully understand the process detailed above:
Trainee: ____________________ Date: __________

By signing below you agree that you feel the technician fully competent at performing the process detailed above:
Qualifier: ____________________ Date: __________

RPh/Technician Training Record

Attachment 8

Competency: Capsules
Trainee: ______________________
Trainer: ______________________ Date: ____________

Procedure	Observation Dates/Initials of trainer*			Demonstration while under observation (Dates/Initials of trainer)**						
1. Calculations										
2. Explain extra precautions needed when making capsules (inhaling powder)										
• List drugs that require special care										
3. Blending powders										
• Name capsule fillers										
• Use of blender										
• Use of mortar (geometric dilution/trituration)										
4. Sieving powders – • Explain why/when sieving powders is necessary										
5. Setting up capsule machine										
• Explain capsule sizes										
• Explain notches on capsule plates and which size capsule goes with each plate										
6. Filling Capsules										
7. %Error Calculation (unless made from tablets)										
8. Clean up										
• Explain why components cannot go into dishwasher										

* Trainee is required to observe at least twice. Additional observation may be necessary, as some trainee's have different levels of experience.

** Trainee is required to be observed at least twice. Additional demonstration may be necessary, as some trainee's have different levels of experience.

By signing below you agree that you fully understand the process detailed above:

Trainee: ______________________ Date: ____________

By signing below you agree that you feel the technician is fully trained and proficient at performing the process detailed above:

Trainer: ______________________ Date: ____________

RPh/Technician Competency Record

Attachment 8

Competency: Capsules
Trainee: ____________________
Qualifier: ____________________ Date: ______________

Procedure	**Qualify**		**Additional Comments**
	Yes	No	
1. Calculations			
2. Explain extra precautions needed when making capsules (inhaling powder)			
• List drugs that require special care			
3. Blending powders			
• Name capsule fillers			
• Use of blender			
• Use of mortar (geometric dilution/trituration)			
4. Sieving powders – • Explain why/when sieving powders is necessary			
5. Setting up capsule machine			
• Explain capsule sizes			
• Explain notches on capsule plates			
6. Filling Capsules			
7. %Error Calculation (unless made from tablets)			
8. Clean up			
• Explain why components cannot go into dishwasher			

By signing below you agree that you fully understand the process detailed above:
Trainee: ____________________ Date: __________

By signing below you agree that you feel the technician is competent performing the process detailed above:
Qualifier: ____________________ Date: __________

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RPh/Technician Training Record

Attachment 9

Competency: Suppositories
Trainee: ______________________
Trainer: ______________________ Date: __________________

Procedure	**Observation Dates/Initials of trainer***			**Demonstration while under observation (Dates/Initials of trainer)****						
1. Calculations										
2. Explain necessary precautions when using silica gel										
3. Sieving powders										
• Explain why sieving powders is necessary										
4. Melting suppository base										
• Explain importance of temperature										
5. Adding sieved powders to melted base										
6. Pouring into suppository shells										
7. Sealing suppository shells										
8. Clean up (proper disposal)										

* Trainee is required to observe at least twice. Additional observation may be necessary, as some trainee's have different levels of experience.

** Trainee is required to be observed at least twice. Additional demonstration may be necessary, as some trainee's have different levels of experience.

By signing below you agree that you fully understand the process detailed above:
Trainee: ______________________________ Date: ___________

By signing below you agree that you feel the technician is fully trained and proficient at performing the process detailed above:
Trainer: ______________________________ Date: ___________

RPh/Technician Competency Record
Attachment 9

Competency: Suppositories
Trainee: ____________________
Qualifier: ____________________ Date: ____________

Procedure	Qualify		Additional Comments
	Yes	No	
1. Calculations			
2. Explain necessary precautions when using silica gel			
3. Sieving powders			
• Explain why sieving powders is necessary			
4. Melting suppository base			
• Explain importance of temperature			
5. Adding sieved powders to melted base			
6. Pouring into suppository shells			
7. Sealing suppository shells			
8. Clean up (proper disposal)			

By signing below you agree that you fully understand the process detailed above:
Trainee: ____________________ Date: ____________

By signing below you agree that you feel the technician is competent performing the process detailed above:
Qualifier: ____________________ Date: ____________

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RPh/Technician Training Record

Attachment 10

Competency: Use of Ointment Mill
Trainee: ____________________________
Trainer: ____________________________ Date: ______________

Procedure	Observation Dates/Initials of trainer*			Demonstration while under observation (Dates/Initials of trainer)**						
1. Explain knobs on mill.										
2. Explain knob settings for:										
• PLO/Van Pen										
• Thick Ointment										
3. Demonstrate milling										
4. Demonstrate how to remove components										
5. Demonstrate how to perform routine cleaning										
6. Describe when soft scrub is used for cleaning										
7. Describe sequence of cleaning solutions when cleaning the mill with soft scrub										

* Trainee is required to observe at least twice. Additional observation may be necessary, as some trainee's have different levels of experience.

** Trainee is required to be observed at least twice. Additional demonstration may be necessary, as some trainee's have different levels of experience.

By signing below you agree that you fully understand the process detailed above:
Trainee: ____________________________ Date: __________

By signing below you agree that you feel the technician is fully trained and proficient at performing the process detailed above:
Trainer: ____________________________ Date: __________

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RPh/Technician Competency Record
Attachment 10

Competency: Use of Ointment Mill
Trainee: ______________________
Qualifier: ______________________ Date: ________________

Procedure	Qualify		Additional Comments
	Yes	No	
1. Explain knobs on mill.			
2. Explain knob settings for:			
• PLO/Van Pen			
• Thick Ointment			
3. Demonstrate milling			
4. Demonstrate how to remove components			
5. Demonstrate how to perform routine cleaning			
6. Describe when soft scrub is used for cleaning			
7. Describe sequence of cleaning solutions when cleaning the mill with soft scrub			

By signing below you agree that you fully understand the process detailed above:
Trainee: ____________________________ Date: __________

By signing below you agree that you feel the technician is fully competent at performing the process detailed above:
Qualifier: ____________________________ Date: __________

ORIGINAL

AWW 03-15-1

TITLE: STERILE COMPOUNDING AREA REQUIREMENTS	
SOP NUMBER: 3.010	**VERSION NUMBER: 2.0**
Sterile Laboratory	Effective Date 03-11-08
Originator:	
Reviewer:	

1.0 PURPOSE

1.1 The purpose of this procedure is to establish requirements for compounding in a sterile environment.

2.0 SCOPE

2.1 This procedure applies to the New England Compounding Center clean room facility under conditions that meet or exceed state and federal guidelines as outlined by the United States Pharmacopeia <797>.

2.2 This procedure must be followed to reduce the amount of particulate matter and airborne microbial contamination.

3.0 RESPONSIBILITY

3.1 The Pharmacist-in-charge shall supervise this procedure or document that another staff member has been designated to complete this task.

3.2 The Pharmacist-in-charge shall be responsible for ensuring that only trained personnel are allowed to work in the sterile compounding area. No other personnel or patients will be allowed within the sterile compounding area.

4.0 REFERENCES

4.1 USP Current Version <797> "Pharmaceutical Compounding – Sterile Preparations"

4.2 SOP 3.020 "Cleaning and Maintenance of the Clean Room Facility"

4.3 SOP 3.030 "Environmental Monitoring of the Clean Room Facility"

5.0 DEFINITIONS

5.1 Clean Room – Area with limited access that is designated for compounding and packaging of compounded sterile preparations (CSPs) and is engineered to meet or exceed Class 1000 (ISO Class 6) standards.

5.2 Gown Room – Area adjacent to the clean room that reduces traffic around the clean room doors and is engineered to meet or exceed Class 10,000 (ISO Class 7) standards.

5.3 Glove Box – Provides no less than a Class 10 (ISO Class 4) working environment for sterile compounding.

5.4 Environmental Monitoring (EM) – Sampling of air and surfaces in critical sites (glove boxes, clean room, crimp room, gown room) in order to confirm compliance with performance objectives and to detect contamination.

6.0 FREQUENCY

6.1 Every 6 months, Class 10 (ISO Class 4), or less, areas shall be re-qualified (glove boxes).

6.2 Every 6 months, Class 1000 (ISO Class 6), or greater, areas shall be re-qualified, and air pressure difference shall be verified (clean room).

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7.0 EQUIPMENT & SUPPLIES

7.1 N/A

8.0 GENERAL INFORMATION

8.1 The air-handling system in the clean room is engineered to provide positive pressure using HEPA filters that reduce particulate matter in order to meet or exceed Class 1000 (ISO Class 6) standards.

9.0 PROCEDURE

9.1 An appropriate clean room shall be used for sterile compounding according to USP <797> guidelines.

9.2 In order to produce a sterile environment in the clean room, the air handling system must create positive pressure (in relation to the anteroom) within the clean room. This environment shall be Class 1000 (ISO Class 6) and shall contain a Class 10 (ISO Class 4) glove box.

9.3 The gown room must provide controlled access to the clean room and must meet or exceed Class 10,000 (ISO Class 7) standards. The gown room must have positive pressure in relation to the outside environment and should have negative pressure in relation to the clean room.

9.4 All surfaces (ceilings, walls, floors, fixtures, shelving, counters, cabinets, etc.) in the clean room must be smooth, impervious, non-shedding and free from cracks and crevices.

9.5 No one may enter the clean room unless appropriate garb is worn.

9.6 Only cleaned and sanitized furniture, equipment, supplies and other goods required for sterile compounding may be brought into any area of the clean room and must be non-permeable, non-shedding and chemically resistant to disinfectants.

9.7 Equipment and similar items used in the clean room shall not be removed from the room except for calibration, servicing or proper maintenance. If equipment or similar items are removed from the clean room, they must be properly cleaned and disinfected before reentering the clean room.

9.8 Clean room cleaning supplies (mops, etc.) shall be designated for use only in the clean room. Cleaning must be performed as per SOP 3.020, "Cleaning and Maintenance of the Clean Room Facility."

9.9 An EM program shall be established, documented and implemented as per SOP 3.030, "Environmental Monitoring of the Clean Room Facility."

10.0 ATTACHMENTS

10.1 N/A

11.0 HISTORY

Version Number	Date Effective	Description of Change	Change Request Number
1.0	03-08-06	New SOP	CR06010
2.0	03-11-08	Changed buffer to clean, other minor changes	CR08008

MMV 03-11-08

TITLE: CLEANING AND MAINTENANCE OF THE CLEAN ROOM FACILITY	
SOP NUMBER: 3.020	**VERSION NUMBER: 9.0**
Sterile Laboratory	Effective Date 06/22/11
Originator:	
Reviewer:	

1.0 PURPOSE

1.1 The purpose of this procedure is to establish requirements and documentation for cleaning and maintenance of the clean room facility.

2.0 SCOPE

2.1 This procedure applies to the New England Compounding Center facility under conditions that meet or exceed state and federal guidelines as outlined by the United States Pharmacopeia <797>. This policy must be followed to reduce the amount of particulate matter and airborne microbial contamination.

3.0 RESPONSIBILITY

3.1 Quality Control shall supervise this procedure and document that all personnel responsible for cleaning and maintenance of the clean room facility shall comply with this procedure.

4.0 REFERENCES

4.1 USP Current Version <797> "Pharmaceutical Compounding – Sterile Preparations"

4.2 SOP 1.060 "General Aseptic Technique"

4.3 SOP 3.030 "Environmental Monitoring of the Clean Room Facility"

4.4 SOP 9.090 "Required Garb for Clean Room Facility Access"

5.0 DEFINITIONS

5.1 N/A

6.0 FREQUENCY

6.1 Cleaning shall be performed as described in this procedure on a daily, weekly and monthly basis.

7.0 EQUIPMENT & SUPPLIES

7.1 Mop with exchangeable mop-head

7.2 Tacky mat

7.3 Lint-free towels or wipes

7.4 Distilled or Purified Water

7.5 2% bleach solution (prepared with 80ml bleach and 1 gallon of distilled water)

7.6 LpH - 1oz (30ml) added to 2 gallons of distilled water

7.7 Vesphene - 2oz (59ml) added to 2 gallons of distilled water

7.8 70% Sterile Isopropyl Alcohol (IPA)

7.9 Sporicide (Sporicidin, Spor-Klenz, or anti-spore solution)

7.10 Waste container liners

7.11 Step stool

7.12 Room thermometer

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7.11 Room hygrometer

8.0 GENERAL INFORMATION

8.1 Cleaning Solutions

8.1.1 Rotation of disinfectants is performed to suppress populations of different types of organisms which may be inherently resistant to one or another type of disinfectant.

8.1.2 LpH and Vesphene, while broad based disinfectants, will be rotated as each has a different pH range which may target different types of organisms. ***(7 day expiration).***

8.1.3 A sporicide will be rotated to suppress spore forming bacteria or mold which is inherently resistant to primary or secondary disinfectants.

8.1.4 Clean floor with 2% bleach solution - to be prepared as needed ***(4 hour expiration).***

8.1.5 Sterile 70% IPA - for use in areas with equipment that may be damaged by the use of bleach. **All IPA designated for use in the clean room facility must be sterile.**

8.2 All primary disinfectants and sporicidal agents require a minimum wet contact time of ten (10) minutes with the surface to which it was applied.

9.0 PROCEDURE

9.1 Follow all applicable SOPs for gowning and transport of materials into the Clean Room Areas.

9.2 Daily - (AM)

9.2.1 Refresh tacky mat.

9.2.2 Clean/sanitize Hoods 1, 2, 3, 4 and 5; Chemo Hood; Horizontal Hoods 1, 2A, 2B, 2C; Glove boxes and Antechambers with sterile 70% IPA.

9.2.3 Clean/sanitize Stations 1, 2, 3, and 4; Tables 1, 2, 3, 4, 5 and 6; including carts, with sterile 70% IPA.

9.2.4 Clean/sanitize balances, hot /stir plates, weigh hoods, computer stations 1 & 2, and telephones, with sterile 70% IPA.

9.2.5 Clean/sanitize sink with Spor-klenz.

9.2.6 Clean/sanitize chairs with sterile 70% IPA.

9.2.7 Document all cleaning on the appropriate attachment.

9.3 During Day

9.3.1 Refresh tacky mat.

9.3.2 Clean/sanitize Hoods 1, 2, 3, 4 and 5; Chemo Hood; Horizontal Hoods 1, 2A, 2B, 2C; Glove boxes and Antechambers with sterile 70% IPA.

9.3.3 Clean/sanitize Stations 1, 2, 3, and 4; Tables 1, 2, 3, 4, 5 and 6; including carts, with sterile 70% IPA.

9.3.4 Clean/sanitize pass-thru, with Spor-klenz or sterile 70% IPA.

9.3.5 Document all cleaning on the appropriate attachment.

9.4 Daily (PM)

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9.4.1 Clean/sanitize Stations 1, 2, 3, and 4; Tables 1, 2, 3, 4, 5 and 6, with Spor-klenz or Sporicidin. Allow to set for at least 10 minutes, disperse with lint-free towels and allow to set overnight.

9.4.2 Clean/sanitize Hood s 1, 2, 3, 4 and 5; Chemo Hood; Horizontal Hoods 1, 2A, 2B, 2C glove boxes and antechambers with Spor-klenz or Sporicidin. Allow to set for at least 10 minutes, disperse with lint-free towels and allow to set overnight.

9.4.3 Clean/sanitize Sink with Spor-klenz or Sporicidin. Allow to set for at least 10 minutes and to set overnight.

9.4.4 Change mop head.

9.4.5 Empty Trash

9.4.4 Mop floors with 2% bleach solution 1 week, alternating with LpH 1 week (Jan → June), rotating with Vesphene (July → Dec).

9.4.6 When using Bleach on metal/stainless steel surfaces, follow with sterile 70% IPA

9.4.6 Document all cleaning on the appropriate attachment.

9.5 Weekly

9.5.1 Clean/sanitize all waste receptacles with Spor-klenz or Sporicidin.

9.5.2 Clean/sanitize entire gown room rotating Spor-klenz and LpH (Jan→June), then spork-lenz and Vesphene (July→Dec).

9.5.3 Clean Autoclave "IN".

9.5.4 Clean Autoclave "OUT".

9.5.5 Document all cleaning on attachment.

9.6 Bi-Weekly

9.6.1 Hepa Vacuum All Rooms (clean room, middle room, gown room).

9.7 Monthly

9.7.1 Clean walls and ceilings. Outside Vendor - **UniClean/Contamination Control Services.**

9.7.2 Clean/sanitize refrigerators/freezers with 70% IPA (sterile).

9.7.3 Clean/sanitize Hood 1 with Spor-Klenz

9.7.4 Clean/sanitize Hood 2 with Spor-Klenz.

9.7.5 Clean/sanitize Hood 3 with Spor-Klenz

9.7.6 Clean/sanitize Hood 4 with Spor-Klenz.

9.7.7 Clean/sanitize Hood 5 with Spor-Klenz

9.7.8 Clean/sanitize Chemo Hood with Spor-Klenz

9.7.9 Clean/sanitize Horizontal 1 Hood with Spor-Klenz

9.7.10 Clean/sanitize Horizontal 2A Hood with Spor-Klenz

9.7.11 Clean/sanitize Horizontal 2B Hood with Spor-Klenz

9.7.12 Clean/sanitize Horizontal 2C Hood with Spor-Klenz

9.7.13 Clean/sanitize Station 1 with Spor-Klenz.

9.7.14 Clean/sanitize Station 2 with Spor-Klenz.

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9.7.15 Clean/sanitize Station 3 with Spor-Klenz.

9.7.16 Clean/sanitize Station 4 with Spor-Klenz.

9.7.17 Clean/sanitize Computer Stations 1 & 2.

9.7.18 Clean/sanitize Alcohol Table with Spor-Klenz.

9.7.19 Clean/sanitize Beaker Shelves with Spor-Klenz.

9.7.20 Clean/sanitize Cap Shelves with Spor-Klenz.

9.7.21 Clean/sanitize Crimp Station with sterile 70% IPA or Spor-Klenz.

9.7.22 Clean/sanitize Luer to Luer /Tamper Evident Cap Shelves with 70% sterile IPA or Spor-Klenz.

9.7.23 Clean/sanitize Nalgene Shelves with 70% sterile IPA or Spor-Klenz.

9.7.24 Clean/sanitize Refrigerators with 70% sterile IPA or Spor-Klenz.

9.7.25 Clean/sanitize Freezers with 70% sterile IPA or Spor-Klenz.

9.7.26 Clean/sanitize Sink Station with 70% sterile IPA or Spor-Klenz.

9.7.27 Clean/sanitize Sterile Cup/Eye Drop Shelves with 70% sterile IPA or Spor-Klenz.

9.7.28 Clean/sanitize Stopper shelves with 70% sterile IPA or Spor-Klenz.

9.7.29 Clean/sanitize Syringe Shelves with 70% sterile IPA or Spor-Klenz.

9.7.30 Clean/sanitize Under Sink with 70% sterile IPA or Spor-Klenz.

9.7.31 Clean/sanitize Drug Shelves 1 with 70% sterile IPA or Spor-Klenz.

9.7.32 Clean/sanitize Drug Shelves 2 with 70% sterile IPA or Spor-Klenz.

9.7.33 Clean/sanitize Drug Shelves 3 with 70% sterile IPA or Spor-Klenz.

9.7.34 Clean/sanitize Drug Shelves 4 with 70% sterile IPA or Spor-Klenz.

9.7.35 Clean/sanitize Drug Shelves 5 with 70% sterile IPA or Spor-Klenz.

9.7.36 Clean/sanitize Drug Shelves 6 with 70% sterile IPA or Spor-Klenz.

9.7.37 Clean/sanitize Miscellaneous Shelves with 70% sterile IPA or Spor-Klenz.

9.7.38 Clean/sanitize Sterile IV Bags Etc...Shelves with Spor-klenz or 70% sterile IPA.

9.7.39 Clean/sanitize Sodium Chloride Bottle Shelves with 70% sterile IPA or Spor-Klenz.

9.7.40 Clean/sanitize Vial Shelves with 70% sterile IPA or Spor-Klenz.

9.7.41 Biannual-Cleaning/Maintenance/Filter changes

9.7.42 Clean/sanitize Hand washer with Spor-klenz or 70% sterile IPA (included in weekly cleaning of the entire gown room).

9.7.43 Change Sterile IPA bottles every six months (May & November).

9.7.44 Change pre-filters on hoods (July)

9.7.45 Clean/sanitize Auto Crimper and hand Crimpers with 70% sterile IPA.

~~9.7.46 Document all cleaning on the appropriate attachment.~~

9.8 Annual Maintenance

9.8.1 Meritech Hand washer Vendor

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9.8.1.1 Twice a year maintenance.

9.9 The necessary cleaning materials are dedicated solely to cleaning the clean room facility. These materials shall be stored in the preparation room of the clean room facility and shall be kept separate from other cleaning materials.

9.10 Cleaning solutions shall be prepared as needed.

9.10.1 Do not combine disinfectants or use them in concentrations other than those outlined in the SOPs.

9.11 Cleaning Solution Preparation

9.11.1 Use only the following approved disinfectants/sporicidal agents. Adjust volumes based on the desired final volume.

- Primary Disinfectants -
    - LpH -1oz (30ml) added to 2 gallons of distilled water.
    - Vesphene - 2oz (59ml) added to 2 gallons of distilled water.
    - Assign a 7 day expiration date from preparation or the manufacturer's expiration, which ever is shorter.
- Secondary Disinfectants
    - Sterile 70% Isopropyl Alcohol (IPA) - purchase as sterile or filter through 0.22um filter.
- Sporicidal Agent
    - 2% bleach (v/v) - 80ml added to 1 gallon of distilled water.(expiration date of 4 hours)
    - Spor-klenz (ready to use) - No preparation required
    - Sporicidin – Disinfectant Towellettes
- Label the solution container with the following information.
    - Solution description
    - Expiration date

9.12 Bucket less Mop System

9.12.1 Dispense the desired solution into the mop's solution tank.

9.12.2 Saturate the mop head by pressing the flow control button.

9.12.3 The mop should leave the surface wet with out pooling.

9.12.4 When mopping, mop in one direction with overlapping strokes.

9.12.5 If solution in apply bucket becomes visibly dirty, change solution.

9.12.6 Refill solution tank when needed.

9.12.7 Discard solution in tank and rinse when cleaning is complete.

9.13 Cleaning solutions shall be prepared as needed.

9.14 Distribute solutions into individual spray bottles for use if needed and label them with the name of the disinfectant.

9.15 Refill bottles with additional disinfectant solution as necessary.

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9.16 All disinfectants solutions (stock or solution spray bottles) shall be discarded at the end of every week to ensure that expired solution is not used and that containers are cleaned.

9.17 Cleaning shall be performed using a detergent followed by sanitization if there are any visible particulates. A damp, non-shedding sponge mop shall be used for cleaning.

9.18 Except for sanitization of the glove box, cleaning of the sterile compounding area is prohibited during compounding operations.

9.18.1 Ensure all compounding operations are completed and all equipment has been removed from the glove box prior to sanitization.

9.18.2 The operator must clean and sanitize the exposed work surfaces (counters and walls) of the glove box immediately before and after each batch preparation and immediately should a spill occur.

9.19 Temperature and humidity readings shall be taken in all areas of the clean room facility.

9.19.1.1 The temperature and humidity in the clean room facility shall be monitored electronically, printed out and placed in a designated binder.

9.19.1.2 The humidity should be maintained in the range of 30% - 50%.

9.19.1.3 The temperature shall be maintained between 60°F- 70°F.

9.19.2 Remove all components (equipment, bottles, adapter caps, filters, syringes, vials, etc.) from the antechambers only. Clean and sanitize with Spor-Klenz at end of day.

9.20 Weekly Requirements

9.20.1 Clean Room includes all requirements listed in section 9.5.

9.20.2 Clean and sanitize gown room and document on the appropriate attachment.

9.20.3 Allow all rooms and equipment to air dry before sterile compounding resumes.

9.20.4 Document all activities on the appropriate Cleaning and Maintenance of the Clean Room Facility forms on Attachments 1, 2 and/or 3. If the equipment is not in use, write "N/A" in the appropriate location on the form.

9.21 Monthly Requirements

9.21.1 Includes all requirements listed in section 9.7.

9.22 The Quality Manager shall ensure the completion of tasks on a daily basis and shall review and sign/date Attachments 1, 2 and 3 at the end of each month. The form shall be retained in the environmental testing binder.

10.0 ATTACHMENTS

10.1 Attachment 1 - Cleaning and Maintenance of the Clean Room - Daily(AM) and **During Day** and Daily(PM)

10.2 Attachment 2 - Cleaning and Maintenance of the Clean Room – Weekly and Monthly

10.3 Attachment 3 – Cleaning and Maintenance of the Clean Room - Monthly

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11.0 HISTORY

Version Number	Date Effective	Description of Change	Change Request Number
1.0	03-08-06	New SOP	CR06011
2.0	04-04-06	Updated section 9.8.4 to include the removal and proper storage of components and equipment from the glove box before daily cleaning.	CR06057
3.0	04-20-06	Modified Attachment 1 for Clean Room 1 Facility. Added Attachment 2 for Clean Room 2 Facility. Updated overall cleaning procedure.	CR06063
4.0	N/A	Added attachment 4	N/A
5.0	11-30-07	Added weekly and monthly duties on separate attachments. Updated changes.	CR07023
6.0	01-24-08	Changes in attachment 2. Needed to specify what was being cleaned.	CR08002
7.0	12/22/08	Updated cleaning and maintenance to fit schedule in clean room	CR08018
8.0	08/31/09	Changed attachments to match equipment.	CR09001
9.0	06/30/11	Updated Changes to match new Clean Room Facility, added a new cleaning attachment, deleted temperature and humidity attachment.	CR11003

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Cleaning and Maintenance of the Clean Room
Month/Year : ____________________

Attachment 1

	M	T	W	R	F	M	T	W	R	F	M	T	W	R	F	M	T	W	R	F	M	T	W	R	F
Date																									
Daily - AM																									
Clean & Sanitize																									
Refresh Tacky Mat																									
H1, H2, H3, H4, H5, Horiz 1, 2A, 2B,2C, Chemo **Glove boxes** and **Antechambers**, with 70% sterile IPA																									
Stations 1, 2, 3, 4, & **Tables** 1, 2, 3, 4, 5, 6, including **Carts** with 70% sterile IPA																									
Balances, Hotplates, Stir Plates, Weigh Hoods, Computer Stations 1 & 2, Telephone, with 70% sterile IPA																									
Chairs with 70% sterile IPA																									
Sink with Spor-klenz																									
During Day																									
Clean & Sanitize																									
Refresh Tacky Mat																									
H1, H2, H3, H4, H5, Horiz 1, 2A, 2B,2C, Chemo **Glove boxes** and **Antechambers**, with 70% sterile IPA																									
Stations 1, 2, 3, 4, & **Tables** 1, 2, 3, 4, 5, 6, including **Carts** with 70% sterile IPA																									
Pass thru, with Spor-klenz or 70% sterile IPA																									
Daily - PM																									
Clean & Sanitize																									
H1, H2, H3, H4, H5, Horiz 1, 2A, 2B,2C, Chemo **Glove boxes** and **Antechambers**, with Spor-klenz or Sporicidin																									
Stations 1, 2, 3, 4, & **Tables** 1, 2, 3, 4, 5, 6, including **Carts** with Spor-klenz or Sporicidin																									
Sink with Spor-klenz or Sporicidin																									
Change Mop head																									
Mop Floors with 2% bleach solution 1 week alternating with LpH 1 week *(Jan-June)*, rotating with Vesphene *(July-Dec)*																									
Empty Trash																									

Quality Control: ______________________________

Reviewed By: ______________________________

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Cleaning and Maintenance of the Clean Room
Month/Year : ____________

Attachment 2

	M	T	W	R	F	M	T	W	R	F	M	T	W	R	F	M	T	W	R	F	M	T	W	R	F
Date																									
Weekly																									
Clean & Sanitize																									
Waste receptacles with Spor-klenz or Sporicidin																									
Rotate Gown Room with Spork-lenz and LpH(Jan→June), then Spork-lenz and Vesphene(July→Dec)																									
Clean Autoclave "IN"																									
Clean Autoclave "OUT"																									
Monthly																									
Alcohol Table						**Sterile Cup/Eye Drop Shelves**										**Sodium Chloride Bottle Shelves**									
Beaker Shelves						**Stopper Shelves**										**Vial Shelves**									
Cap Shelves						**Syringe Shelves**										**Bi-Weekly**									
Crimp Station						**Under Sink**										Hepa **Vacuum** ***ALL*** rooms									
Luer to luer/Tamper Evident Cap Shelves						**Drug Shelves 1**																			
Nalgene Shelves						**Drug Shelves 2**										**Monthly** - Clean Walls/Ceilings (OUTSIDE VENDOR)									
Refrigerator Station 2						**Drug Shelves 3**										**Quarterly** - Full *Maintenance/Filter Changes (Victory)*									
Refrigerator						**Drug Shelves 4**										Change Sterile IPA Bottles						**MAY**	**NOV**		
Refrigerator/Freezer						**Drug Shelves 5**										Autoclaves						**JAN**	**JULY**		
2 Small Freezers						**Drug Shelves 6**										Hand Washers				**Biannually**	**Meritech Vendor**				
Sink Station						**Miscellaneous Shelves**										PRE-FILTERS on HOODS							**JULY**		
Auto Crimper/ Hand Crimpers						**Sterile IV Bags, Etc. Shelves**																			

Quality Control: ______________________

Reviewed By: ______________________

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Cleaning and Maintenance of the Clean Room

Month/Year : ____________________

Attachment 3

	M	T	W	R	F	M	T	W	R	F	M	T	W	R	F	M	T	W	R	F	M	T	W	R	F
Date																									
Monthly																									
CLEAN & SANITIZE with 70% sterile IPA or Spor-klenz																									
STATION 1																									
STATION 2																									
STATION 3																									
STATION 4																									
COMPUTER STATION 1																									
COMPUTER STATION 2																									
HOOD 1																									
HOOD 2																									
HOOD 3																									
HOOD 4																									
HOOD 5																									
CHEMO																									
HORIZ 1																									
HORIZ 2A																									
HORIZ 2B																									
HORIZ 2C																									

Quality Control: ____________________

Reviewed By: ____________________

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TITLE: ENVIRONMENTAL MONITORING OF THE CLEAN ROOM FACILITY	
SOP NUMBER: 3.030	**VERSION NUMBER: 4.0**
Sterile Laboratory	Effective Date 09-22-08
Originator:	
Reviewer:	

1.0 PURPOSE

1.1 The purpose of this procedure is to establish requirements for viable and non-viable environmental monitoring (EM) of the clean room facility.

2.0 SCOPE

2.1 This procedure applies to the New England Compounding Center clean room facility under conditions that meet or exceed state and federal guidelines as outlined by the United States Pharmacopeia <797>.

2.2 This procedure must be followed to reduce the amount of particulate matter and airborne microbial contamination.

3.0 RESPONSIBILITY

3.1 The Pharmacist-in-charge shall supervise this procedure and document that all personnel responsible for EM of the clean room facility comply with this procedure.

4.0 REFERENCES

4.1 USP Current Version <797> "Pharmaceutical Compounding – Sterile Preparations"

4.2 USP Current Version <1116> "Microbiological Evaluation of Clean Rooms and Other Controlled Environments"

4.3 ISO 14644-4 "Clean Rooms and Associated Controlled Environments", Part 4

4.4 SOP 3.010 "Sterile Compounding Area Requirements"

4.5 SOP 3.020 "Cleaning and Maintenance of the Clean Room Facility"

4.6 SOP 9.090 "Required Garb for Clean Room Facility Access"

5.0 DEFINITIONS

5.1 CFU – Colony forming unit

5.2 Viable Particle - A viable particle is a particle that contains one or more living microorganisms.

5.3 Viable Air Sampler - Device used to sample microorganisms in the air.

5.4 Non-Viable Air Sampling - Total particle count. Includes viable particles but does not test for presence of microorganisms.

5.5 Surface Contact Plate - Agar plate used to sample surfaces for microorganisms by direct application. The agar contains neutralizers to inactivate residual disinfectants.

5.6 ISO Classifications

   5.6.1 ISO Class 4 is equivalent to Class 10 (glove box, antechamber).

   5.6.2 ISO Class 6 is equivalent to Class 1,000 (main clean room).

   5.6.3 ISO Class 7 is equivalent to Class 10,000 (gown/crimp room).

   4.1.1 ISO Class 8 is equivalent to Class 100,000 (prep room).

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5.7 Alert Level -Signals a potential drift from normal operating conditions when normal levels of viable particulate in a controlled environment are exceeded; reaching alert level does not require investigation. (Attachment 8)

5.8 Action Level - Signals a potential drift from normal operating conditions when normal levels of viable particulate in a controlled environment are exceeded; reaching action level requires an investigation and corresponding corrective action. (Attachment 8)

6.0 FREQUENCY

6.1 Personnel touch plates shall be sampled upon completion of sterile compounding and **prior to cleaning.**

6.2 Surface sampling in the glove boxes and antechambers Class 10(ISO Class 4), Class 1000 main clean room(ISO Class 6), Class10,000(ISO Class 7) gown/crimp room, Class100,000(ISO Class 8)prep room, area shall be performed weekly, **prior to cleaning.**

6.3 Sterility of 70% isopropyl alcohol (IPA) will be confirmed weekly.

6.4 Viable air sampling shall be performed weekly.

6.5 Non-Viable air sampling shall be performed at least every six months.

6.6 The Pharmacist-in-charge or the Quality Control officer shall review EM data at least every six months to ensure no adverse trends exist.

7.0 EQUIPMENT & SUPPLIES

7.1 Contracted third party (if applicable)

7.2 TSA contact plates containing lecithin and polysorbate 80

7.3 Viable air sampler with sterilized impeller and shroud (Model # SAS180)

7.4 Appropriate user manuals

7.5 Sterile compounding garb

8.0 GENERAL INFORMATION

8.1. EM should flow from "clean" areas to "dirty" areas.

9.0 PROCEDURE

9.1 Upon receipt of commercially prepared TSA contact plates, retain the manufacturer's Certificate of Analysis (CofA). Document receipt of the media on Receipt of Contact plates (Attachment 1).

9.2 Verify that the (CofA) documents the manufacturer's testing of growth promotion. If documentation is not provided, quarantine the media and do not use until appropriate certification is received.

  9.2.1 Remove two plates from new lot of media received for positive and negative controls.

  9.2.2 Label one plate "Positive" and the other plate "Negative," and write the date on each plate.

  9.2.3 Do not expose the agar surface of the "Negative" plate. Seal the contact plate with parafilm.

  9.2.4 For the "Positive" control expose the agar to air for 15 minutes. Seal the contact plate with parafilm.

  9.2.5 Incubate for 5 days at 30°C-35°C. Document on Attachment 1.

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9.2.6 If the positive control has no growth or the negative control has growth, the lot must be rejected.

9.2.7 Place the completed Attachment 1, along with the (CofA) in a designated binder.

9.2.8 Store all acceptable media according to the manufacturer's recommendation in a monitored refrigerator. (2°C - 8°C).

9.3 Viable Air Sampling

9.3.1 Set up the air sampler according to the manufacturer's instructions.

9.3.2 Sanitize the exterior of the air sampler prior to use with a low-lint wipe, saturated with sterile 70% IPA.

9.3.3 If the sampler is being moved from a dirty to clean location during sampling, repeat exterior sanitization.

9.3.4 Make sure the air sampler is programmed with the following parameters:

Sample Time	Air Volume/Minute	Total Air Volume
5.5 Minutes	180 Liters	1000 liters (35ft^3)

9.3.5 Don all appropriate clean room garb and gloves as per SOP 9.090, "Required Garb for Clean Room Facility Access." Be sure to periodically sanitize gloves with sterile 70% IPA while sampling.

9.3.6 Document all data on the appropriate Attachments.

9.3.7 Obtain the appropriate quantity of media from storage.

9.3.7.1 Inspect each plate and discard any damaged or contaminated media and replace.

9.3.7.2 Verify media is within expiration date and record media lot number and expiration date on Attachment 6.

9.3.7.3 Aseptically remove an agar contact plate from its package. Make sure that the contact plate covers remains on.

9.3.7.4 Aseptically remove the outer protective cap from the sampler and unscrew the aspirating head.

9.3.7.5 Secure the plate between the metal prongs. Once secure, remove the contact plate cover and immediately replace the aspirating head and screw on tightly.

NOTE: *Do not touch the agar surface (If agar is touched, discard the contact plate).*

9.3.8 Place the air sampler in the desired location at cart or bench top height. Orient the air sampler in a vertical position facing the ceiling and turn on.
Do not place arms over sampler while in operation.

9.3.8.1 The air sampler will automatically turn off at the conclusion of the sampling period.

9.3.8.2 Aseptically remove the contact plate from the sampler. Replace the lid of the contact plate.

9.3.8.2.1 Inspect the contact plate to ensure the impingement marks are present.

9.3.8.2.2 If impingement marks are not present, the sample is invalid and shall be repeated with a new contact plate.

9.3.8.3 Seal the contact plate with parafilm.

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9.3.8.4 Record the site location on the base of the plate, initial and date. Do not record any information on the cover plate.

9.3.8.5 Invert the samples and incubate for as follows.

9.3.8.6 5 days at 30-35 °C.

NOTE: If 5th day of incubation falls on a non-business day, then the plates shall be incubated at that temperature for the remainder of the 7 days. Do not exceed 7 days of incubation.

NOTE: Samples may be shipped to a contract lab for incubation and analysis.

9.4 Non-Viable Air Sampling

9.4.1 Non-viable air sampling shall be performed every 6 months along with Room/Hood Certification.

9.4.2 Sampling shall be performed by an approved vendor using calibrated equipment.

9.4.3 File all completed documents in the designated binder.

9.5 Surface Sampling

9.5.1 Document all data on the appropriate Attachments.

9.5.2 Surface sampling in the glove boxes and antechambers - Class 10 (ISO 4), Class 1000 (ISO 6)main clean room, Class 10,000 (ISO 7)gown/crimp room, Class 100,000 (ISO 8) prep room area shall be performed weekly, **prior to cleaning**

9.5.3 Obtain the appropriate quantity of contact plates from storage.

9.5.3.1 Inspect each plate and discard any damaged or contaminated media and replace.

9.5.3.2 Verify media is within expiration date and record media lot number and expiration date on appropriate Attachment.

9.5.4 Don all appropriate clean room garb and gloves as per SOP 9.090, "Required Garb for Clean Room Facility Access". Be sure to periodically sanitize gloves with sterile 70% IPA while sampling.

9.5.5 Sampling technique:

9.5.5.1 Aseptically remove the contact plate cover and hold the contact plate face down. Gently touch the agar to the desired surface and roll the plate slightly to ensure complete contact with the surface for 10 seconds.

9.5.5.2 Replace the cover and seal the plate with parafilm.

9.5.5.3 Record the site location on the base of the plate. Do not record any information on the cover of the plate.

9.5.5.4 Clean the sample site with sterile 70% IPA before proceeding to the next site.

9.5.6 Incubate for 5 days 30°C-35°C.

9.5.7 Record surface sampling results on Attachment 2, and file all completed documents in the EM binder.

9.6 Confirm the Sterility of 70% IPA

9.6.1 Refer to the appropriate Attachment for Surface Sampling Log

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9.6.2 Obtain two contact plates from storage and test two random sterile 70% IPA bottles.

9.6.2.1 Inspect each plate and discard any damaged or contaminated media and replace.

9.6.2.2 Verify media is within expiration date, and record media lot number and expiration date on Attachment 2.

9.6.3 Aseptically remove the contact plate cover.

NOTE: *Do not touch the agar surface (If agar is touched, discard the contact plate).*

9.6.4 Spray the surface of the agar with the sterile 70% IPA designated for use in the clean room.

9.6.5 Replace the cover and seal the plate with parafilm.

9.6.6 Label the base of the plate with "IPA" and the IPA lot number/expiration date. Do not record any information on the cover of the plate.

9.6.7 Incubate for 5 days at 30°C-35°C.

9.6.8 Record results on Attachment 2, and file all completed documents in the EM binder.

9.7 Personnel Monitoring

9.7.1 Refer to the Clean Room Facility Personnel Touch Plate Log (Attachment 7).

9.7.2 Obtain the appropriate quantity of contact plates from storage.

9.7.2.1 Inspect each plate and discard any damaged or contaminated media and replace.

9.7.2.2 Verify media is within expiration date.

9.7.2.3 Label the base of the contact plate with the date, the pharmacist/technician initials, the hand sampled and what product is being compounded.

9.7.2.4 After sterile compounding is completed for the day, and **prior to cleaning**, touch each gloved finger of the dominant hand to the agar surface, making certain not to re-touch areas.

9.7.3 Replace the cover and seal the plate with parafilm.

9.7.4 Incubate for 5 days at 30°C-35°C.

9.7.5 Record personnel monitoring results on Attachment 7 and file all completed documents in the EM binder.

9.8 The Pharmacist-in-charge or the Quality Control Officer shall review EM data at least every six months to ensure no adverse trends exist.

9.9 Alert and Action Limits

9.9.1 Air Sampling (Viable)

9.9.2 Calculate the level of viable airborne particulates as CFU per cubic foot. The volume of air sampled in the Class 10 (ISO 4) area will be 284 liters (10 cubic feet) and all other locations will be 142 liters (5 cubic feet).

9.9.2.1 The alert/action limits for air sampling should be derived from historical data. * **Until historical data can be determined, follow the guidelines provided by the USP Proposed Levels for Air and Surface Monitoring (Attachment 8).**

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9.9.3 Surface and Personnel Monitoring

9.9.3.1 Calculate the level of surface and personnel particles as CFU per contact plate.

9.9.3.2 The alert/action limits for surface and personnel monitoring should be derived from historical data. * **Until historical data can be determined, follow the guidelines provided by the USP Proposed Levels for Air and Surface Monitoring (Attachment 8).**

9.10 Investigation and Corrective Actions

9.10.1 **There will be no alert/action levels until historical data can be collected to set appropriate levels. Data should be collected for a minimum of one month prior to setting limits. After one year the levels should be re-evaluated to take into account seasonal changes.**

9.10.2 If an alert level is exceeded, corrective action may not be required, but records should demonstrate that a spike in normal levels was recognized.

9.10.3 If alert levels are consistently exceeding the limits (three consecutive samplings), the Pharmacist-in-charge or Quality Control Officer must be notified and investigation and corrective action should occur. This may include, but is not limited to, the following actions:

9.10.3.1 Review of sanitation procedures

9.10.3.2 Review of sampling technique

9.10.3.3 Review of clean room personnel

9.10.3.4 Inspection of sampling media

9.10.4 If an excursion occurs above an action level, the Pharmacist-in-charge or Quality Control Officer must be notified and investigation and corrective action should occur. This may include, but is not limited to, the following actions:

9.10.4.1 Identification of microbial isolates to determine origin

9.10.4.2 Review of pressure differential information

9.10.4.3 Review of HEPA and clean room certification

9.10.4.4 Review of Logs of Use, Maintenance and Cleaning (LUMACs)

9.10.5 After the corrective action is taken, the area should be re-sampled three consecutive times. If all samples are within limits, approve the corrective action. If any sample fails, additional investigation is required.

9.11 Non-Routine Samples

9.11.1 Non-routine samples that are not listed on the Viable and Surface Sampling Forms may be taken at a desired location.

9.11.2 Take the sample according to the appropriate air or surface sampling procedure above.

9.11.3 Document air/surface sample location and results on Attachment 4.

9.11.4 Non-routine samples are investigational and shall not be compared to alert/action values. Do not generate an alert or action as described in 9.10 for non-routine samples.

9.12 Reporting Results

9.12.1 Remove samples from the incubator. Record stop times on the appropriate attachment.

9.12.2 Count all colonies on the plate and document results for each category below.

- Bacteria
- Mold (Count or indicate presence)
- Total Counts of Bacteria and Mold combined

10.0 ATTACHMENTS

10.1 Attachment 1 - Receipt of Contact Plates
10.2 Attachment 2 - Clean Room Surface Sampling
10.3 Attachment 3 - Clean Room Surface Sampling Diagram
10.4 Attachment 4 - Random Air/Surface Sample Form
10.5 Attachment 5 - Clean Room Viable Air Sampling Diagram
10.6 Attachment 6 - Clean Room Viable Air Sampling
10.7 Attachment 7 - Clean Room Facility Personnel Touch Plate Log
10.8 Attachment 8 - Levels for Air and Surface Monitoring

1.0 HISTORY

Version Number	Date Effective	Description of Change	Change Request Number
1.0	03-08-06	New SOP	CR06012
2.0	04/06/06	Updated section 9.3 and attachment 1 to include positive/negative controls. Updated sample identification labels and schematic maps on attachments 2, 3, 4 and 5.	CR06053
3.0	11/30/07	Taking out TSA Strips, non-viable samples, fixing iso/ classes not correct	CR07018
4.0	09-22-08	Re did attachments for new clean room, Minor changes	CR08017

TITLE: ENVIRONMENTAL MONITORING OF THE CLEAN ROOM FACILITY
SOP NUMBER: 3.030 **VERSION NUMBER:** 4.0

RECEIPT OF CONTACT PLATES - ATTACHMENT 1

Quantity Rec'd (i.e. boxes of 50 plates)	*Manufacturer*	*Lot Number*	*Expiration Date*	*Received By (Initials/Date)*	*Incubation Dates of Positive and Negative Controls 30°C-35°C*	*Positive Control*	*Negative Control*	*Results (CFU)*
					Incubation for 5 days at 30°C-35°C	☐ Growth	☐ Growth	☐ Accept
					→	☐ No Growth	☐ No Growth	☐ Reject
					Incubation for 5 days at 30°C-35°C	☐ Growth	☐ Growth	☐ Accept
					→	☐ No Growth	☐ No Growth	☐ Reject
					Incubation for 5 days at 30°C-35°C	☐ Growth	☐ Growth	☐ Accept
					→	☐ No Growth	☐ No Growth	☐ Reject
					Incubation for 5 days at 30°C-35°C	☐ Growth	☐ Growth	☐ Accept
					→	☐ No Growth	☐ No Growth	☐ Reject
					Incubation for 5 days at 30°C-35°C	☐ Growth	☐ Growth	☐ Accept
					→	☐ No Growth	☐ No Growth	☐ Reject
					Incubation for 5 days at 30°C-35°C	☐ Growth	☐ Growth	☐ Accept
					→	☐ No Growth	☐ No Growth	☐ Reject

Quality Control: ____________________ Date: ____________________
Reviewed By: ____________________ Date: ____________________

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CLEAN ROOM SURFACE SAMPLING

Page 1 of 2

Sample Location	Description	Results			Alert/Action
		Bacteria CFU	Mold CFU	Total CFU	
H1	Hood 1				☐ Alert ☐ Action
H1AC1	Hood 1 Antechamber (Right Side)				☐ Alert ☐ Action
H1AC2	Hood 1 Antechamber (Left Side)				☐ Alert ☐ Action
H2	Hood 2				☐ Alert ☐ Action
H2AC3	Hood 2 Antechamber (Right Side)				☐ Alert ☐ Action
H2AC4	Hood 2 Antechamber (Left Side)				☐ Alert ☐ Action
H3	Hood 3				☐ Alert ☐ Action
H3AC5	Hood 3 Antechamber (Right Side)				☐ Alert ☐ Action
H3AC6	Hood 3 Antechamber (Left Side)				☐ Alert ☐ Action
H4	Hood 4				☐ Alert ☐ Action
H4AC7	Hood 4 Antechamber				☐ Alert ☐ Action
H5	Hood 5				☐ Alert ☐ Action
CHEMO	Chemo Hood				☐ Alert ☐ Action
HORIZ 1	Horizontal 1				☐ Alert ☐ Action
HORIZ 2A	Horizontal 2A				☐ Alert ☐ Action
HORIZ 2B	Horizontal 2B				☐ Alert ☐ Action
HORIZ 2C	Horizontal 2C				☐ Alert ☐ Action
STATION 1	Station 1				☐ Alert ☐ Action
STATION 2	Station 2				☐ Alert ☐ Action
STATION 3	Station 3				☐ Alert ☐ Action
STATION 4	Station 4				☐ Alert ☐ Action
PASS THRU	Pass Thru				☐ Alert ☐ Action
TABLE 1	Table 1				☐ Alert ☐ Action
TABLE 2	Table 2				☐ Alert ☐ Action
TABLE 3	Table 3				☐ Alert ☐ Action
TABLE 4	Table 4				☐ Alert ☐ Action
TABLE 5	Table 5				☐ Alert ☐ Action
TABLE 6	Table 6				☐ Alert ☐ Action
COMP. ST. 1	Computer Station 1				☐ Alert ☐ Action
COMP. ST. 2	Computer Station 2				☐ Alert ☐ Action

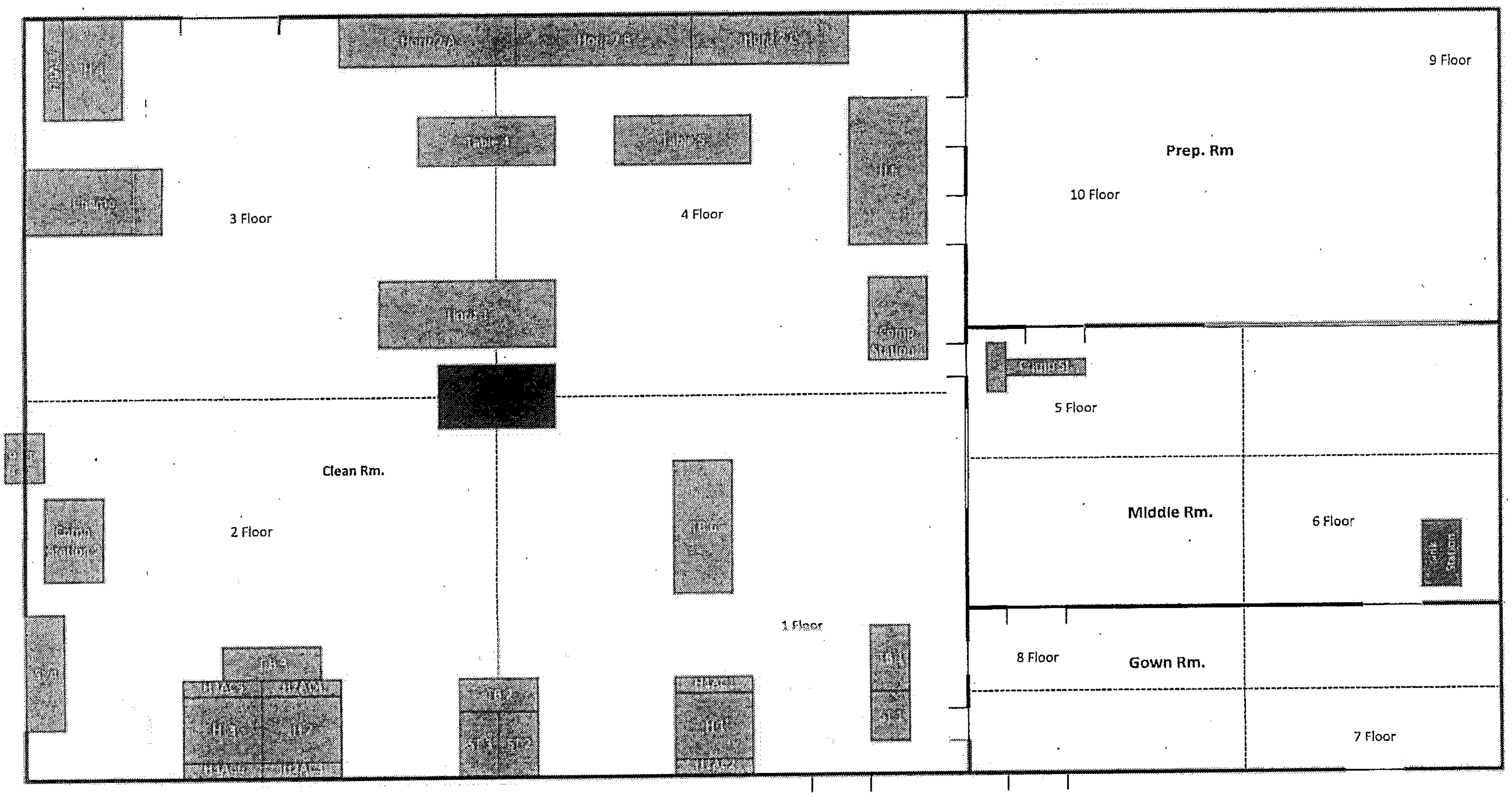
Quality Control: ______________________ Date: ______________________

Reviewed By: ______________________ Date: ______________________

			Results		
Sample Location	Description	Bacteria CFU	Mold CFU	Total CFU	Alert/Action
SINK STATION	Sink Station				☐ Alert ☐ Action
CRIMP STATION	Crimp Station				☐ Alert ☐ Action
WALL CR 1	Clean Room Wall 1				☐ Alert ☐ Action
WALL CR 2	Clean Room Wall 2				☐ Alert ☐ Action
WALL MR 1	Middle Room Wall 1				☐ Alert ☐ Action
WALL MR 2	Middle Room Wall 2				☐ Alert ☐ Action
WALL GR 1	Gown Room Wall 1				☐ Alert ☐ Action
WALL GR 2	Gown Room Wall 2				☐ Alert ☐ Action
WALL PREP 1	Prep Room 1				☐ Alert ☐ Action
WALL PREP 2	Prep Room 2				☐ Alert ☐ Action
1FLR	1 Floor (near hood 1)				☐ Alert ☐ Action
2FLR	2 Floor (near hood 3)				☐ Alert ☐ Action
3FLR	3 Floor (near horizontal hoods)				☐ Alert ☐ Action
4FLR	4 Floor (near hood 5)				☐ Alert ☐ Action
5FLR	5 Floor (near crimp bench)				☐ Alert ☐ Action
6FLR	6 Floor (near sink)				☐ Alert ☐ Action
7FLR	7 Floor (gown room - entrance)				☐ Alert ☐ Action
8FLR	8 Floor (gown room - near hooks)				☐ Alert ☐ Action
9FLR	9 Floor (prep room - near entrance)				☐ Alert ☐ Action
10FLR	10 Floor (prep room - near big Pass Thru				☐ Alert ☐ Action
RANDOM/BINCR1	1 Clean room bin or random surface				☐ Alert ☐ Action
RANDOM/BINCR2	2 Clean room bin or random surface				☐ Alert ☐ Action
RANDOM/BINMR1	1 Middle room bin or random surface				☐ Alert ☐ Action
RANDOM/BINMR2	2 Middle room bin or random surface				☐ Alert ☐ Action
RANDOM/BINPREP1	1 Prep room bin or random surface				☐ Alert ☐ Action
RANDOM/BINPREP2	2 Prep room bin or random surface				☐ Alert ☐ Action
SINK STATION	Sink Station				☐ Alert ☐ Action
CRIMP STATION	Crimp Station				☐ Alert ☐ Action
1IPA	Alcohol				☐ Alert ☐ Action
2IPA	Alcohol				☐ Alert ☐ Action

Quality Control: ______________________ Date: ______________

Reviewed By: ______________________ Date: ______________



Two Random Walls:
- Clean Room
- Middle Room
- Gown Room
- Prep Room

Two IPA bottles once a month

Two Misc Random
- Clean Room
- Middle Room
- Gown Room
- Prep Room

Two Drug Bins in Clean Room

TITLE: ENVIRONMENTAL MONITORING OF THE CLEAN ROOM FACILITY
SOP NUMBER: 3.030 **VERSION NUMBER:** 4.0

RANDOM AIR/SURFACE SAMPLING - ATTACHMENT 4

Air/Surface Sample Location	Description	Results		
		Bacteria CFU	*Mold CFU*	*Total CFU*

Date of Sampling: ________________ Media Lot#: ________________ Exp Date: ____________
Sampler Mfg/Model: ________________________ Calibration Due Date: ____________________

Quality Control: ____ Date: ________________________

Reviewed By: ____ Date: ________________________

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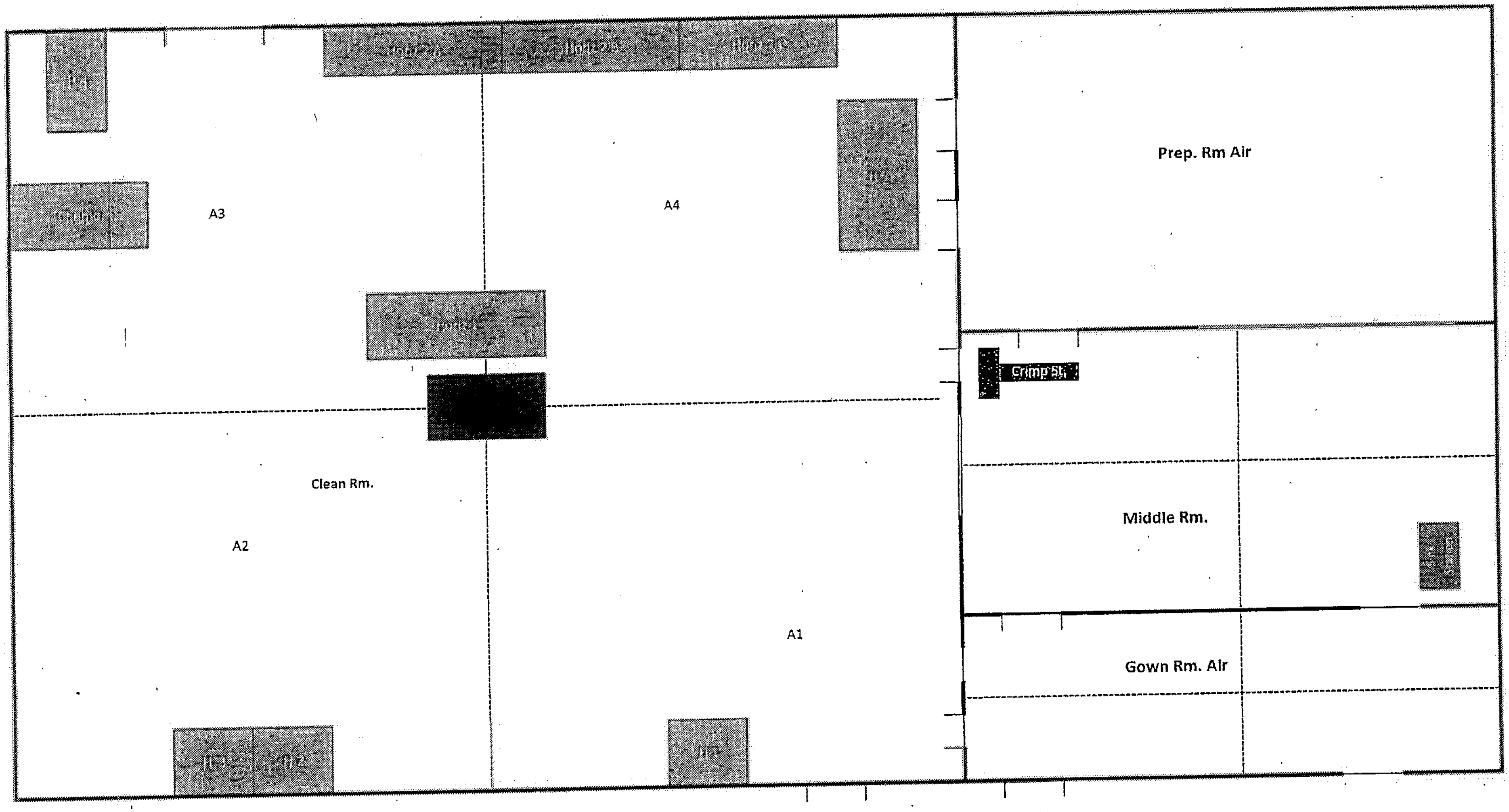
Hood 2A
Hood 2B
Hood 2C
A3
A4
Hood 1
Clean Rm.
A2
A1
Prep. Rm Air
Crimp St.
Middle Rm.
Gown Rm. Air

Clean Room Air Sampling

		Results			
Sample Location	Description	Bacteria CFU	Mold CFU	Total CFU	Alert/Action
H1	Hood 1				☐ Alert ☐ Action
H2	Hood 2				☐ Alert ☐ Action
H3	Hood 3				☐ Alert ☐ Action
H4	Hood 4				☐ Alert ☐ Action
H5	Hood 5				☐ Alert ☐ Action
CHEMO	Chemo				☐ Alert ☐ Action
HORIZ 1	Horizontal 1				☐ Alert ☐ Action
HORIZ 2A	Horizontal 2A				☐ Alert ☐ Action
HORIZ 2B	Horizontal 2B				☐ Alert ☐ Action
HORIZ 2C	Horizontal 2C				☐ Alert ☐ Action
A1	By entrance & Hood 1				☐ Alert ☐ Action
A2	By hood 3 & Pass thru				☐ Alert ☐ Action
A3	By chemo & horiz 1				☐ Alert ☐ Action
A4	By horiz 2C & hood 5				☐ Alert ☐ Action
CRIMP STATION	Crimp Station				☐ Alert ☐ Action
SINK STATION	Sink Station				☐ Alert ☐ Action
GOWN ROOM	Gown Room				☐ Alert ☐ Action
PREP ROOM	Prep Room				☐ Alert ☐ Action

Quality Control: ______________________ Date: ____________

Reviewer: ______________________ Date: ____________

CLEAN ROOM FACILITY PERSONNEL TOUCH PLATE LOG - ATTACHMENT 7

Media Lot # and Exp Date	Rph/Tech	Location and Product Being worked on	Incubation for 5 days at 30°C - 35°C	Results (CFU)	Alert / Action
			→		☐ Al ☐ Ac
			→		☐ Al ☐ Ac
			→		☐ Al ☐ Ac
			→		☐ Al ☐ Ac
			→		☐ Al ☐ Ac
			→		☐ Al ☐ Ac
			→		☐ Al ☐ Ac
			→		☐ Al ☐ Ac
			→		☐ Al ☐ Ac
			→		☐ Al ☐ Ac
			→		☐ Al ☐ Ac

Alert Level 1+ CFU
Action Level 2+ CFU

Quality Control: ______________________ Date: ______________

Reviewed By: ______________________ Date: ______________

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TITLE: ENVIRONMENTAL MONITORING OF THE CLEAN ROOM FACILITY
SOP NUMBER: 3.030 VERSION NUMBER: 4.0

LEVELS FOR AIR AND SURFACE MONITORING - ATTACHMENT 8

*Note: ** Alert/Action Levels are to be determined after historical data is collected***

Levels for Air Sampling

Classifications	Alert Level	Action Level
ISO 4 (Class 10) Glove box, Antechambers	1 CFU	2+ CFU
ISO 6 (Class 1,000) Main Clean Room	2 CFU	3+ CFU
ISO 7(Class 10,000) Gown room, Crimp Room	5 CFU	8+ CFU
ISO Class 8 (Class 100,000) Prep Room	8 CFU	10+ CFU

Levels for Surface Sampling

Classifications			Alert Level	Action Level
ISO 4 (Class 10) Glove box, Antechambers			1 CFU	2+ CFU
ISO 6 (Class 1,000) Main Clean Room			3 CFU	5+ CFU
ISO 7(Class 10,000) Gown room, Crimp Room			5 CFU	7+ CFU
ISO Class 8 (Class 100,000) Prep Room			8 CFU	10+CFU

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LEVELS FOR AIR AND SURFACE SAMPLING

*Note: ** Alert/Action Levels are to be determined after historical data is collected***

Levels for Air Sampling

Classifications	Alert Level	Action Level
ISO 4 (Class 10) Glove box, Antechambers	1 CFU	2+ CFU
ISO 6 (Class 1,000) Main Clean Room	2 CFU	4+ CFU / 9+ CFU (by hood 1)
ISO 7(Class 10,000) Gown room, Crimp Room	5 CFU	8+ CFU
ISO Class 8 (Class 100,000) Prep Room	8 CFU	10+ CFU

Levels for Surface Sampling
RECEIPT OF CONTACT PLATES

Classifications	Alert Level	Action Level
ISO 4 (Class 10) Glove box, antechambers	1 CFU	2+ CFU
ISO 6 (Class 1,000) Main Clean Room	3 CFU	5+ CFU
ISO 7(Class 10,000) Gown room, Crimp Room	5 CFU	7+ CFU
ISO Class 8 (Class 100,000) Prep Room	8 CFU	10+CFU

TITLE: NON-STERILE COMPOUNDING AREA REQUIREMENTS	
SOP NUMBER: 3.040	**VERSION NUMBER: 1.0**
Non-Sterile Laboratory	Effective Date 03-08-06
Originator:	
Reviewer:	

1.0 PURPOSE

1.1 The purpose of this procedure is to establish requirements for compounding in a non-sterile environment.

2.0 SCOPE

2.1 This procedure applies to the New England Compounding Center non-sterile compounding area under conditions that meet or exceed state and federal guidelines as outlined by the United States Pharmacopeia <795>.

2.2 This procedure must be followed to reduce the amount of particulate matter and airborne microbial contamination.

3.0 RESPONSIBILITY

3.1 The Pharmacist-in-charge shall supervise this procedure or document that another staff member has been designated to complete this task.

3.2 The Pharmacist-in-charge shall be responsible for ensuring that only trained personnel are allowed to work in the non-sterile compounding area. No other personnel or patients will be allowed within this area unless wearing appropriate clothing and under strict supervision.

4.0 REFERENCES

4.1 USP Current Version <795> "Pharmaceutical Compounding – Non-Sterile Preparations"

4.2 SOP 3.050 "Cleaning and Maintenance of the Non-Sterile Compounding Area"

5.0 DEFINITIONS

5.1 N/A

6.0 FREQUENCY

6.1 N/A

7.0 EQUIPMENT & SUPPLIES

7.1 N/A

8.0 GENERAL INFORMATION

8.1 N/A

9.0 PROCEDURE

9.1 Areas designated for non-sterile compounding must have adequate space for orderly placement of equipment and materials to prevent cross-contamination.

9.2 Areas for sterile and non-sterile compounding must be separated and distinct.

9.3 Non-sterile compounding areas should be maintained in a clean and sanitary condition.

9.4 The non-sterile compounding area should be well lit and should have appropriate storage areas.

9.5 Heating, ventilation and air conditioning should be controlled at all times.

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TITLE: NON-STERILE COMPOUNDING AREA REQUIREMENTS

SOP NUMBER: 3.040 **VERSION NUMBER: 1.0**

9.6 Equipment should be cleaned promptly after use.

10.0 ATTACHMENTS

10.1 N/A

11.0 HISTORY

Version Number	Date Effective	Description of Change	Change Request Number
1.0	03-08-06	New SOP	CR06013

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TITLE: CLEANING AND MAINTENANCE OF THE NON-STERILE COMPOUNDING AREA	
SOP NUMBER: 3.050	**VERSION NUMBER: 6.0**
Non-Sterile Laboratory	Effective Date 03/16/12
Originator:	
Reviewer:	

1.0 PURPOSE

1.1 The purpose of this procedure is to establish requirements for the cleaning and maintenance of the non-sterile compounding area.

2.0 SCOPE

2.1 This procedure applies to the New England Compounding Center non-sterile compounding area under conditions that meet or exceed state and federal guidelines as outlined by the United States Pharmacopeia <795>.

2.2 This procedure must be followed to reduce the amount of particulate matter and airborne microbial contamination.

3.0 RESPONSIBILITY

3.1 The Pharmacist-in-charge shall supervise this procedure and document that all non-sterile compounding personnel will comply with this procedure.

4.0 REFERENCES

4.1 USP Current Version <795> "Pharmaceutical Compounding – Non-Sterile Preparations"

4.2 SOP 1.050 "General Compounding Technique"

4.3 SOP 4.010 "Compounding Equipment"

4.4 SOP 4.020 "Use, Calibration and Maintenance of the Drug Product Refrigerator and Freezer"

4.5 SOP 9.020 "Good Documentation Practices (GDP)"

4.6 SOP 9.120 "Required Garb for Non-Sterile Compounding Area"

5.0 DEFINITIONS

5.1 PPE – Personnel Protective Equipment

6.0 FREQUENCY

6.1 Daily (when non-sterile compounding activities are planned)

- 6.1.1 Sanitize pass- thru with 70% IPA
- 6.1.2 Sanitize all horizontal surfaces and sink with 70% IPA.
- 6.1.3 Record temperature and humidity of laboratory (two times a day).
- 6.1.4 Record temperature of drug product refrigerator/freezer.
- 6.1.5 Clean all in-use powder hoods with appropriate cleaner.
- 6.1.6 Wipe down all in-use equipment with 70% IPA.
- 6.1.7 Clean all utensils after use (by placing in dishwasher).
- 6.1.8 Remove and discard trash.
- 6.1.9 Peel off one layer of tacky mat (or more often if necessary).

6.2 Weekly

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- 6.2.1 Perform daily requirements listed in section 6.1
- 6.2.2 Vacuum Floors
- 6.2.3 Mop floors with AJAX® All Purpose Cleaner (1/4 cup to 1 gallon warm water)
- 6.2.4 Sanitize waste receptacles with 70% IPA
- 6.2.5 Clean bench tops with 70% IPA
- 6.2.6 Clean sink with "Bar Keepers Friend" (cleanser)
- 6.2.7 Restock lab once a week

6.3 Monthly

- 6.3.1 Perform daily requirements listed in section 6.1
- 6.3.2 Perform weekly requirements listed in section 6.2
- 6.3.3 Clean bench tops with 2% bleach solution, followed by 70% IPA
- 6.3.4 Clean and sanitize the refrigerator/freezer with 2% bleach solution
- 6.3.5 Clean and sanitize medication rack with 2% bleach solution
- 6.3.6 Mop floor with 2% bleach solution (prepared with 80ml bleach and 1 gallon of distilled water) (expiration date of 4 hours)

6.4 Quarterly

- 6.4.1 Scales/Fume Hood- Section #1
- 6.4.2 Middle Section and Drugs- Section #2
- 6.4.3 Sink/Walls- Section #3
- 6.4.4 Cream Room- Section #3

7.0 EQUIPMENT & SUPPLIES

- 7.1 Proper Personnel Protective Equipment (PPE) (bouffant, mask, booties, disposable gown or frock, gloves, and safety glasses, if appropriate.
- 7.2 Disposable mop head
- 7.3 Tacky mat
- 7.4 Paper towels
- 7.5 AJAX® All Purpose Cleaner (1/4 cup to 1 gallon warm water)
- 7.6 2% Bleach Solution (prepared with 80 ml bleach and one gallon of dH20) (expiration date of 4 hours)
- 7.7 70% isopropyl alcohol (IPA)
- 7.8 Waste container liners
- 7.9 Step stool
- 7.10 Room thermometer
- 7.11 ~~Room hygrometer~~
- 7.12 Distilled or purified water
- 7.13 Sporicidin

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8.0 GENERAL INFORMATION

8.1 Cleaning Solutions

8.1.1 2% bleach solution (prepared with 80 ml bleach and one gallon of distilled water, expiration - date 4 hours).

8.1.2 70% IPA - For use with equipment that may be damaged by the use of bleach.

8.1.3 AJAX® All Purpose Cleaner (1/4 cup to 1 gallon warm water).

9.0 PROCEDURE

9.1 Personnel must wear appropriate PPE when cleaning. At minimum, gloves and eye protection is required.

9.2 Cleaning solutions shall be prepared as needed.

9.2.1 Do not combine solutions or use them in concentrations other than those outlined in the SOPs.

9.3 Except for sanitization of the workbenches, utensils or equipment, cleaning of the non-sterile compounding area is prohibited during compounding operations.

9.3.1 Ensure all compounded preparations are completed.

9.3.2 The operator must clean and sanitize the exposed work surfaces before and after each batch preparation and immediately, should a spill occur, with appropriate sanitizer.

9.4 The order of cleaning within the non-sterile compounding area is as follows:

9.4.1 Hoods (powder hood)

9.4.2 Non-sterile compounding area

9.5 Daily Requirements (when non-sterile compounding activities are planned)

9.5.1 Peel off layer of tacky mat.

9.5.2 Temperature and humidity readings shall be taken in the non-sterile compounding area.

9.5.2.1 The temperature shall be maintained between 60°F–70°F.

9.5.2.2 The humidity should be maintained in the range of 15%–50%.

9.5.2.3 Record Temperature and Humidity on "Temperature and Humidity Monitoring of the Non-Sterile Compounding Area log (Attachment 2).

9.5.2.4 Calibrate electronic balances, initial and date print out and attach to the "Daily/Monthly Calibration Log" (SOP 4.030) and record initials on calibration log, as well.
NOTE: The scale must be leveled. Make sure the bubble on the scale is in the center of the circle. If it needs to be adjusted, adjust the feet in the back of the scale, accordingly.

9.5.2.5 Turn on hoods and computers.

9.5.3 Record drug product refrigerator/freezer temperature on Attachment 1/2 on SOP 4.020, "Use, Calibration and Maintenance of the Drug Product Refrigerator and Freezer."

9.5.4 Clean and sanitize countertops/sinks with 70% IPA.

9.5.5 Clean and sanitize equipment as needed. Document equipment cleaning on appropriate cleaning log as per SOP 4.010, "Compounding Equipment."

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9.5.6 Clean and sanitize plastic bins used to transport drug preparation with 70% IPA before compounding.

9.5.7 Allow all surfaces and equipment to air dry before non-sterile compounding resumes.

9.5.8 Order supplies as necessary.

9.5.9 At the end of the day:

9.5.9.1 Check supplies and straighten up the non-sterile compounding area.

9.5.9.2 Turn off all equipment and computer as required.

9.5.9.3 Empty all waste receptacles by removing the filled plastic bag.

9.5.10 Document all activities on the Cleaning and Maintenance of the Non-Sterile Compounding Lab log sheet (Attachment 1). If the equipment is not in use, write "N/A" in the appropriate location on the form.

9.6 Weekly Requirements

9.6.1 Includes all requirements listed in section 9.5.

9.6.2 Clean and sanitize countertops with 70% IPA.

9.6.3 Clean and sanitize sink with cleanser, if needed, followed by a 2% bleach solution.

9.6.4 Wipe waste receptacles with 70% IPA, let dry and place a clean plastic bag in the receptacle.

9.6.5 Vacuum Floors

9.6.6 AJAX® All Purpose Cleaner (1/4 cup to 1 gallon warm water).

9.6.7 Restock laboratory weekly.

9.6.8 Document all activities on the Cleaning and Maintenance of the Non-Sterile Compounding Lab log (Attachment 1).

9.7 Monthly Requirements

9.7.1 Includes all requirements listed in sections 9.5 and 9.6.

9.7.2 Clean and sanitize countertops with 2% bleach solution, followed by 70% IPA.

9.7.3 Clean and sanitize the drug product refrigerator/freezer with 2% bleach solution.

9.7.4 Clean and sanitize the medication racks with sporicidin wipes.

9.8 Quarterly Requirements

9.8.1 Lab will be divided into four sections- Each section's shelves and bins need to be cleaned with 2% bleach solution, followed by 70% IPA.

9.8.2 Document all activities on the Cleaning and Maintenance of the Non-Sterile Compounding lab log sheet (Attachment 1).

9.9 Cleaning can be performed as often as needed, but the minimum requirement is at the end of the day ***after*** compounding.

9.10 The Pharmacist/Supervisor-in-charge/QC shall ensure the completion of tasks on a daily basis and shall review and sign/date Attachment 1 at the end of each month. The form shall be retained in a cleaning/maintenance binder.

ORIGINAL
MMK 2-16-12

10.0 ATTACHMENTS

10.1 Attachment 1 – Cleaning and Maintenance of the Non-Sterile Compounding Lab

10.2 Attachment 2 – Temperature and Humidity Monitoring of the Non-Sterile Compounding Area

11.0 HISTORY

Version Number	Date Effective	Description of Change	Change Request Number
1.0	04/10/06	New SOP	CR06014
2.0	04/12/06	Updated attachments and clarified cleaning regimen	CR06061
3.0	11/02/07	Attachment 1 changes, updates	CR07016
4.0	08/04/08	Changed Attachment 1, added cleaning of pass through, minor other changes	CR08013
5.0	06/10/11	Updated changes	CR11001
6.0	03/16/12	Changes needed to fit our move. Non-sterile lab is not connected to the sterile lab anymore.	CR12002

ORIGINAL
3-16-12

TEMPERATURE AND HUMIDITY MONITORING OF THE NON-STERILE COMPOUNDING AREA

Month/Year: ______________________________

Temperature Range: 60°F-70°F **Humidity Range:** 15%-50%

Date	Time	Temperature (°F)	Humidity (%)	Initials

Quality Control: ______________________________ **Date:** ______________

Reviewer: ______________________________ **Date:** ______________

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AWR 6-3-16

Cleaning and Maintenance of Non-Sterile Compounding Lab

Month/Year: ____________________

DATE	M	T	W	R	F	M	T	W	R	F	M	T	W	R	F	M	T	W	R	F	M	T	W	R	F
DAILY																									
Tacky Mat																									
Clean Counters (70% IPA)																									
Clean Sink (70% IPA)																									
Pass-thru (70% IPA)																									
Order lab supplies																									
Trash																									
Recycle																									
Dishwasher																									
WEEKLY																									
Trash bins cleaned(70% IPA)																									
Clean sink (cleanser)																									
Bench tops with 70% IPA																									
Vacuum																									
Mop floors - AJAX® (1/4 cup to 1 gallon warm water).																									
Restock lab (1x/wk)																									
MONTHLY																									
Bench tops(2% bleach solution, than 70% IPA																									
Refrigerator/freezer (2% bleach)																									
Medication rack (sporicidin wipes)																									
Mop floors with 2% bleach(80ml bleach/1 gallon water-exp.date 4 hrs)																									
Shelves, bins and floors - 2% bleach sol'n(80ml bleach to 1 gal dH20-exp date 4 hrs) JANUARY/APRIL/JULY/OCTOBER																									
QUARTERLY																									
Section #1 Scales/Fume Hood																									
Section #2 Middle section & Drugs																									
Section #3 Sink/Walls																									
Section #4 Cream Room																									

Quality Control: ____________________ Date: ____________________

Reviewer: ____________________ Date: ____________________

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03-10-11

TITLE: CLEANING AND MAINTENANCE OF CLEAN ROOM 2 FACILITY	
SOP NUMBER: 3.060	**VERSION NUMBER: 1.0**
Sterile Laboratory	Effective Date 07-31-12
Originator:	
Reviewer:	

1.0 PURPOSE

1.1 The purpose of this procedure is to establish requirements and documentation for cleaning and maintenance of the clean room 2 facility.

2.0 SCOPE

2.1 This procedure applies to the New England Compounding Center facility under conditions that meet or exceed state and federal guidelines as outlined by the United States Pharmacopeia <797>. This policy must be followed to reduce the amount of particulate matter and airborne microbial contamination.

3.0 RESPONSIBILITY

3.1 Quality Control shall supervise this procedure and document that all personnel responsible for cleaning and maintenance of the clean room 2 facility shall comply with this procedure.

4.0 REFERENCES

4.1 USP Current Version <797> "Pharmaceutical Compounding – Sterile Preparations"

4.2 SOP 1.060 "General Aseptic Technique"

4.3 SOP 3.030 "Environmental Monitoring of the Clean Room Facility"

4.4 SOP 9.090 "Required Garb for Clean Room Facility Access"

5.0 DEFINITIONS

5.1 N/A

6.0 FREQUENCY

6.1 Cleaning shall be performed as described in this procedure on a daily, weekly and monthly basis.

7.0 EQUIPMENT & SUPPLIES

7.1 Mop with exchangeable mop-head

7.2 Tacky mat

7.3 Lint-free towels or wipes

7.4 Distilled or Purified Water

7.5 2% bleach solution (prepared with 80ml bleach and 1 gallon of distilled water)

7.6 LpH - 1oz (30ml) added to 2 gallons of distilled water

7.7 Vesphene - 2oz (59ml) added to 2 gallons of distilled water

7.8 70% Sterile Isopropyl Alcohol (IPA)

7.9 Sporicide (Sporicidin, Spor-Klenz, or anti-spore solution)

7.10 Waste container liners

7.11 Step stool

7.12 Room thermometer

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7.11 Room hygrometer

8.0 GENERAL INFORMATION

8.1 Cleaning Solutions

8.1.1 Rotation of disinfectants is performed to suppress populations of different types of organisms which may be inherently resistant to one or another type of disinfectant.

8.1.2 LpH and Vesphene, while broad based disinfectants, will be rotated as each has a different pH range which may target different types of organisms. ***(7 day expiration).***

8.1.3 A sporicide will be rotated to suppress spore forming bacteria or mold which is inherently resistant to primary or secondary disinfectants.

8.1.4 Clean floor with 2% bleach solution - to be prepared as needed ***(4 hour expiration).***

8.1.5 Sterile 70% IPA - for use in areas with equipment that may be damaged by the use of bleach. **All IPA designated for use in the clean room facility must be sterile.**

8.2 All primary disinfectants and sporicidal agents require a minimum wet contact time of ten (10) minutes with the surface to which it was applied.

9.0 PROCEDURE

9.1 Follow all applicable SOPs for gowning and transport of materials into the Clean Room Areas.

9.2 Daily- (AM)

9.2.1 Refresh tacky mat.

9.2.2 Place Liners in trash barrels and spray with 70% sterile IPA. Clean tables and carts with 70 % sterile IPA.

9.2.3 Clean/sanitize Hoods H56, Horizontal L, R, W and F with 70% sterile IPA.

9.2.4 Clean/sanitize tables and carts with 70 % sterile IPA.

9.2.5 Clean/sanitize pass thru's with Spor-klenz and/or 70 % sterile IPA.

9.2.6 Clean/sanitize balances, hot /stir plates, weigh hoods, computer station and telephone, with sterile 70% IPA.

9.2.7 Clean/sanitize chairs with sterile 70% IPA.

9.2.8 Clean/sanitize sink with Spor-klenz and with 70 % sterile IPA.

9.2.9 Document all cleaning on the appropriate attachment.

9.3 During Day

9.3.1 Refresh tacky mat.

9.3.2 Clean/sanitize Hoods H56, Horiz L, R, W and F with 70% sterile IPA.

9.3.3 Clean/sanitize tables, carts and pass-thru's with 70 % sterile IPA or Spor-klenz.

9.3.4 Document all cleaning on the appropriate attachment.

9.4 Daily (PM)

9.4.1 Clean/sanitize Sink with Spor-klenz or Sporicidin. Allow to set for at least 10 minutes. Clean with 70% sterile IPA to set overnight.

9.4.2 Change mop head.

9.4.3 Empty trash barrels and spray with Spor-klenz.

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9.4.4 Mop floors with 2% bleach solution 1 week, alternating with LpH 1 week (Jan → June), rotating with Vesphene (July → Dec).

9.4.4 When using Bleach on metal/stainless steel surfaces, follow with sterile 70% IPA.

9.4.6 Document all cleaning on the appropriate attachment.

9.5 Weekly

9.5.1 Clean/sanitize all waste receptacles with Spor-klenz or Sporicidin.

9.5.2 Clean/sanitize entire gown room with Vesphene

9.5.3 Hepa Vacuum All Rooms (clean room, middle room, gown room)

9.5.4 Clean/sanitize large pass-thru with Spor-klenz. Allow to set for at least 10 minutes. Clean with 70% sterile IPA to set overnight. Spray the cart with Vesphene.

9.5.5 Document all cleaning on appropriate attachment.

9.6 Monthly

9.6.1 Clean walls and ceilings. Outside Vendor - **UniClean/Contamination Control Services.**

9.6.2 Clean/sanitize Hood 56 with Spor-Klenz

9.6.3 Clean/sanitize Powder hood with Sporicidin.

9.6.4 Clean/sanitize Horizontal L with Spor-Klenz.

9.6.5 Clean/sanitize Horizontal R with Spor-Klenz

9.6.6 Clean/sanitize Horizontal W with Spor-Klenz.

9.6.7 Clean/sanitize Horizontal F with Spor-Klenz.

9.6.8 Clean/sanitize refrigerators/freezers with 70% sterile IPA (sterile).

9.6.9 Clean/sanitize incubator with 70% sterile IPA

9.6.10 Clean/sanitize Shelving #1 with Spor-Klenz

9.6.11 Clean/sanitize Shelving #2 with Spor-Klenz

9.6.12 Clean/sanitize Shelving #3 with Spor-Klenz

9.6.13 Clean/sanitize Shelving #4 with Spor-Klenz

9.6.14 Clean/sanitize Shelving #5 with Spor-Klenz.

9.6.15 Clean/sanitize Shelving #6 with Spor-Klenz.

9.6.16 Clean/sanitize Station Computer Station with 70% sterile IPA

9.6.17 Clean/sanitize Table 1 and 2 with Spor-Klenz.

9.6.18 Clean/sanitize Carts 70% sterile IPA.

9.6.19 Clean/sanitize Middle room Shelving 1 Spor-Klenz.

9.6.20 Clean/sanitize Middle room Shelving 2 Spor-Klenz

9.6.21 Clean/sanitize ETOH Shelf Spor-Klenz.

9.6.22 Biannual-Cleaning/Maintenance/Filter changes

9.6.23 Clean/sanitize Hand washer with Spor-klenz or 70% sterile IPA (included in weekly cleaning of the entire gown room).

9.6.24 Change pre-filters on hoods (July)

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9.6.25 Document all cleaning on the appropriate attachment.

9.7 Annual Maintenance

9.7.1 Meritech Hand washer Vendor

9.7.1.1 Twice a year maintenance.

9.8 The necessary cleaning materials are dedicated solely to cleaning the clean room facility. These materials shall be stored in the preparation room of the clean room facility and shall be kept separate from other cleaning materials.

9.9 Cleaning solutions shall be prepared as needed.

9.9.1 Do not combine disinfectants or use them in concentrations other than those outlined in the SOPs.

9.10 Cleaning Solution Preparation

9.10.1 Use only the following approved disinfectants/sporicidal agents. Adjust volumes based on the desired final volume.

- Primary Disinfectants -
    - LpH -1oz (30ml) added to 2 gallons of distilled water.
    - Vesphene - 2oz (59ml) added to 2 gallons of distilled water.
    - Assign a 7 day expiration date from preparation or the manufacturer's expiration, which ever is shorter.
- Secondary Disinfectants
    - Sterile 70% Isopropyl Alcohol (IPA) - purchase as sterile or filter through 0.22um filter.
- Sporicidal Agent
    - 2% bleach (v/v) - 80ml added to 1 gallon of distilled water.(expiration date of 4 hours)
    - Spor-klenz (ready to use) - No preparation required
    - Sporicidin – Disinfectant Towellettes
- Label the solution container with the following information.
    - Solution description
    - Expiration date

9.11 Bucket less Mop System

9.11.1 Dispense the desired solution into the mop's solution tank.

9.11.2 Saturate the mop head by pressing the flow control button.

9.11.3 The mop should leave the surface wet with out pooling.

9.11.4 When mopping, mop in one direction with overlapping strokes.

9.11.5 If solution in apply bucket becomes visibly dirty, change solution.

9.11.6 Refill solution tank when needed.

9.11.7 Discard solution in tank and rinse when cleaning is complete.

9.12 Cleaning solutions shall be prepared as needed.

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9.13 Distribute solutions into individual spray bottles for use if needed and label them with the name of the disinfectant.

9.14 Refill bottles with additional disinfectant solution as necessary.

9.15 All disinfectants solutions (stock or solution spray bottles) shall be discarded at the end of every week to ensure that expired solution is not used and that containers are cleaned.

9.16 Cleaning shall be performed using a detergent followed by sanitization if there are any visible particulates. A damp, non-shedding sponge mop shall be used for cleaning.

9.16.1 Except for sanitization of Hood 56 and the Horizontal hood s L, R, W and F, cleaning of the sterile compounding area is prohibited during compounding operations.

9.17 Temperature and humidity readings shall be taken in all areas of the clean room facility.

9.17.1.1 The temperature and humidity in the clean room facility shall be monitored electronically, printed out and placed in a designated binder.

9.17.1.2 The humidity should be maintained in the range of 30% - 60%.

9.17.2 The temperature shall be maintained between 60°F- 70°F.

9.18 Weekly Requirements

9.18.1 Clean Room includes all requirements listed in section 9.5.

9.18.2 Clean and sanitize gown room and document on the appropriate attachment.

9.18.3 Allow all rooms and equipment to air dry before sterile compounding resumes.

9.18.4 Document all activities on the appropriate Cleaning and Maintenance of Clean Room 2 Facility forms on Attachments 1 and 2. If the equipment is not in use, write "N/A" in the appropriate location on the form.

9.19 Monthly Requirements

9.19.1 Includes all requirements listed in section 9.7.

9.20 The Quality Manager shall ensure the completion of tasks on a daily basis and shall review and sign/date Attachments 1and 2 at the end of each month. The form shall be retained in the environmental testing binder.

10.0 ATTACHMENTS

10.1 Attachment 1 - Cleaning and Maintenance of the Clean Room - Daily(AM) and **During Day** and Daily(PM)

10.2 Attachment 2 - Cleaning and Maintenance of the Clean Room – Weekly and Monthly

11.0 HISTORY

Version Number	Date Effective	Description of Change	Change Request Number
1.0	07-31-12	New SOP	NA

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Cleaning and Maintenance of Clean Room 2 Attachment 1

Month/Year : ____________

	M	T	W	R	F	M	T	W	R	F	M	T	W	R	F	M	T	W	R	F	M	T	W	R	F
Date																									
Daily - AM																									
Clean & Sanitize																									
Refresh **Tacky Mat**																									
Place **Liners** in Trash barrels - Spray 70% sterile IPA																									
H56, Horiz L, R, W and **F** - 70% sterile IPA																									
Tables and **Carts** -70% sterile IPA																									
Pass thru's - Spor-klenz and 70% sterile IPA																									
Balances, Hotplates, Stir Plates, Weigh Hoods, Computer Station, Telephone- 70% sterile IPA																									
Chairs - 70% sterile IPA																									
Sink - Spor-klenz & 70% sterile IPA																									
During Day																									
Clean & Sanitize																									
Refresh **Tacky Mat**																									
H56, Horiz L, R , W and **F**, - 70% sterile IPA																									
Tables,carts & pass thru-Spor-klenz or 70% sterile IPA																									
Daily - PM																									
Clean & Sanitize																									
Sink - Spor-klenz or Sporicidin																									
Change **Mop head**																									
Mop floors - 2% bleach solution 1 week,alternating with LpH 1 week*(Jan→June)* rotating with Vesphene(July→Dec)																									
Empty **Trash barrels**, Spray - Spor-klenz																									

Quality Control: ____________

Reviewed By: ____________

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Cleaning and Maintenance of Clean Room 2 Attachment 2

Month/Year : ____________________

	M	T	W	R	F	M	T	W	R	F	M	T	W	R	F	M	T	W	R	F	M	T	W	R	F
Date																									
Weekly																									
Clean & Sanitize																									
Entire Gown Room - Vesphene																									
Large Pass Thru - Spor-klenz																									
Hepa Vacuum Clean room, Middle room, Gown room, Crimp room & Prep room																									
Monthly																									
CLEAN & SANITIZE with 70% sterile IPA or Spor-klenz																									
Shelving #1						H56										**Monthly** - Clean Walls/Ceilings (OUTSIDE VENDOR)									
Shelving #2						Horizontal Right																			
Shelving #3						Horizontal Left										**Biannual** - Cleaning/Maintenance/Filter changes									
Shelving #4						Horizontal Window										Hand Washers **Biannually/ Meritech Vendor**									
Shelving #5						Horizontal Front										Wall Filters **Jan/July**									
Shelving #6						Refrigerator/Freezer										PRE-FILTERS on HOODS **July**									
Computer/Telephone Station						Incubator																			
Table1						Middle Room Shelving 1																			
Table2						Middle Room Shelving 2																			
ETOH Shelf						Carts																			

Quality Control: ____________________

Reviewed By: ____________________

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TITLE: COMPOUNDING EQUIPMENT	
SOP NUMBER: 4.010	**VERSION NUMBER: 2.0**
Non-Sterile and Sterile laboratory	Effective Date 09-20-07
Originator:	
Reviewer:	

1.0 PURPOSE

1.1 The purpose of this procedure is to establish requirements for all equipment utilized in the compounding process that requires calibration, verification and maintenance.

2.0 SCOPE

2.1 This procedure applies to all compounding personnel at New England Compounding Center.

3.0 RESPONSIBILITY

3.1 The Pharmacist-in-charge shall supervise this procedure or document that another staff member has been designated to complete the task.

4.0 REFERENCES

4.1 SOP 1.040 "Log of Maintenance and Cleaning (L-MAC)"

4.2 SOP 3.020 "Cleaning and Maintenance of the Clean Room Facility"

4.3 SOP 3.050 "Cleaning and Maintenance of the Non-Sterile Compounding Area"

4.4 Equipment user manuals

5.0 FREQUENCY

5.1 Standard operating procedures (SOPs) should be created upon introduction of new compounding equipment and should be updated accordingly.

6.0 DEFINITIONS

6.1 L-MAC – Log of Maintenance and Cleaning

7.0 EQUIPMENT & SUPPLIES

7.1 Equipment manuals (if applicable)

8.0 GENERAL INFORMATION

8.1 There shall be a SOP for all equipment utilized in the compounding process that requires calibration, verification and maintenance.

9.0 PROCEDURE

9.1 A SOP shall be created for each piece of equipment utilized in the compounding process that requires calibration, monitoring of function, maintenance and control.

9.2 The SOP shall include, but not be limited to, the following items:

- 9.2.1 Cleaning
- 9.2.2 Care and maintenance
- 9.2.3 Operation or reference to manual
- 9.2.4 Calibration/verification (if appropriate)
- 9.2.5 Validation (if appropriate)

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9.3 All compounding personnel shall be properly trained on all of the equipment he or she will utilize in the compounding process.

9.4 All appropriate equipment must have a corresponding L-MAC.

9.5 Equipment shall be cleaned daily prior to use.

  9.5.1 Document cleaning on Attachment 1, 2 and 3 of SOP 3.020, "Cleaning and Maintenance of the Clean Room Facility," for all equipment used in the clean room.

  9.5.2 Document cleaning on Attachment 1 of SOP 3.050, "Cleaning and Maintenance of the Non-Sterile Compounding Area," for all equipment used in the non-sterile compounding area.

9.6 Equipment shall be thoroughly cleaned immediately following use to avoid cross-contamination of product.

  9.6.1 Equipment for which there is no specific cleaning procedure must be wiped down thoroughly with 70% sterile IPA (sterile clean room) and 70% IPA (non-sterile laboratory).

10.0 ATTACHMENTS

10.1 N/A

11.0 HISTORY

Version Number	Date Effective	Description of Change	Change Request Number
1.0	03-28-06	New SOP	CR06015
2.0	09-20-07	Updated, Took out Attachment #1	CR07006

Remainder of this page intentionally left blank.

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09-20-07

TITLE: USE, CALIBRATION AND MAINTENANCE OF THE DRUG PRODUCT REFRIGERATOR AND FREEZER	
SOP NUMBER: 4.020	**VERSION NUMBER: 3.0**
Non-Sterile and Sterile Laboratory	Effective Date 07-06-11
Originator:	
Reviewer:	

1.0 PURPOSE

1.1 The purpose of this procedure is to outline the use, calibration and maintenance of the drug product refrigerator and freezer.

2.0 SCOPE

2.1 This procedure applies to all compounding personnel utilizing the drug product refrigerator and freezer at New England Compounding Center.

3.0 PERSONNEL

3.1 The Pharmacist-in-charge shall supervise this procedure and document that all compounding personnel will comply with this procedure.

4.0 REFERENCES

4.1 USP Current Version <797> ""Pharmaceutical Compounding – Sterile Preparations"

4.2 SOP 3.020 "Cleaning and Maintenance of the Clean Room Facility"

4.3 SOP 3.050 "Cleaning and Maintenance of the Non-Sterile Compounding Area"

4.4 Refrigerator manual

4.5 Freezer manual

5.0 DEFINITIONS

5.1 N/A

6.0 FREQUENCY

6.1 Temperature monitoring shall be completed once daily during normal business hours.

6.2 Cleaning of the drug product refrigerator and freezer shall be completed monthly as noted in the lab cleaning SOPs (SOP 3.020 and SOP 3.050).

6.3 Maintenance shall be performed if necessary according to the manufacturer's specifications.

7.0 EQUIPMENT/MATERIALS

7.1. Calibrated refrigerator/freezer thermometer

7.2 Cleaning and disinfecting solution (2% Bleach Solution, Sterile 70% IPA, 70% IPA and Windex).

8.0 GENERAL INFORMATION

8.1 N/A

9.0 PROCEDURE

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9.1 Use and Daily Monitoring

9.1.1 When items must be placed in or removed from the drug product refrigerator/freezer, the door should not remain open for an extended period. Items should be added or removed quickly, and the door should be shut immediately.

9.1.2 A digital refrigerator/freezer thermometer shall be positioned in the middle of one of the drug product refrigerator/freezer shelves, or as near to the center as possible.

9.1.3 The designated temperature range for the drug product refrigerator and freezer (according to USP <797>) is 2°C to 8°C and -20°C to -10°C, respectively. The appropriate temperature range should be clearly labeled on the drug product refrigerator/freezer.

9.1.4 Daily temperature readings of the drug product refrigerator and freezer shall be recorded on Attachment 1 and Attachment 2.

9.1.5 If the observed temperature of the drug product refrigerator/freezer does not fall within the designated range, drug products must be removed immediately and placed in an alternate, properly calibrated drug product refrigerator/freezer.

9.1.6 Discard any products damaged by the variation in temperature.

9.1.7 At the end of month, the daily monitoring logs shall be reviewed by Quality Control and the Pharmacist-in-charge. It shall be retained in a quality assurance file.

10.0 Cleaning Sterile Clean Room

10.1 Remove any materials that may be harmed by the temperature change that will occur when the refrigerator/freezer door is open for cleaning and place them in another calibrated refrigerator/freezer.

10.2 The interior bottom, sides and shelves of the unit should be cleaned using sterile 70% IPA.

10.3 Allow the interior to dry thoroughly before closing the unit and replace all items that were removed for cleaning.

10.4 The exterior should be cleaned using a sterile 70% IPA.

10.5 Document monthly cleaning of the drug product refrigerator and freezer according to SOP 3.020, "Cleaning and Maintenance Clean Room Facility."

11.0 Cleaning Non-Sterile Laboratory

11.1.1 Remove any materials that may be harmed by the 2% bleach solution or by the temperature change that will occur when the refrigerator/freezer door is open for cleaning and place them in another calibrated refrigerator/freezer.

11.1.2 The interior bottom, sides and shelves of the unit should be cleaned using 2% bleach solution.

11.1.3 Allow the interior to dry thoroughly before closing the unit and replace all items that were removed for cleaning.

~~11.1.4 The exterior should be cleaned using a 2% bleach solution.~~

11.1.5 Document monthly cleaning of the drug product refrigerator and freezer according to SOP 3.050, "Cleaning and Maintenance of the Non-Sterile Compounding Area."

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12.0 All refrigerators and freezers in the packing area are to be cleaned with Windex as needed.

12.1 Freezers for ice packs are to be defrosted weekly. Drug freezer as needed.

12.2 Calibration (when installing **new** refrigerator/freezer)

12.2.1 A calibrated refrigerator/freezer thermometer, that can be read externally, shall be positioned near the center of the refrigerator/freezer.

12.2.2 Allow one hour for the thermometer to equilibrate with the environment.

12.2.3 When one hour has elapsed, read the thermometer. If the reading does not fall within the desired temperature range, adjust the refrigerator/freezer temperature control accordingly. If the reading does fall within the desired temperature range, proceed to step 12.2.7.

12.2.4 Allow one hour for the refrigerator/freezer to adjust to the new setting and allow for the thermometer to equilibrate with the environment.

12.2.5 Repeat steps 12.2.2 and 12.2.3 until an appropriate temperature is achieved.

12.2.6 An entire cooling cycle must be observed to make certain that the extremes fall within the designated temperature range. If the designated temperature range cannot be obtained, drug products must be removed immediately and placed in an alternate drug product refrigerator/freezer, and further investigation is required.

12.2.7 All temperature readings shall be recorded on the Drug Product Refrigerator Daily monitoring Log (Attachment 1) or on the Drug Product Freezer Daily Monitoring Log (Attachment 2).

12.2.8 Each completed daily monitoring log shall be placed in a quality assurance file.

12.3 Maintenance

12.3.1 Maintenance of the drug product refrigerator/freezer shall be performed according to the manufacturer's specifications, as needed.

12.3.2 The drug product refrigerator/freezer should be defrosted to prevent build-up of ice on the coils, as needed.

12.3.3 Check circulating fans for excessive noise and build-up of lint on the blades.

12.3.4 Wipe off the door gasket and inspect for cracks.

12.4 **ATTACHMENTS**

12.5 Attachment 1 – Drug Product Refrigerator Daily Monitoring Log

12.6 Attachment 2 – Drug Product Freezer Daily Monitoring Log

AMK 7-06-11

13.0 HISTORY

Version Number	Date Effective	Description of Change	Change Request Number
1.0	03/28/06	New SOP	CR06016
2.0	12/20/07	Minor updates and changes	CR07026
3.0	07/06/11	Added Windex for cleaning, adjusted the margin numbers, corrected a few errors, took out the refrigerator/freezer calibration logs	CR11004

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DRUG PRODUCT REFRIGERATOR DAILY MONITORING LOG

Refrigerator ID/Location: ______________________________

Month/Year: ____________________ Appropriate Temperature Range: *2°C to 8°C*

Week	Day	Date	Time	Refrigerator Temperature (°C)	Initials
1	Mon				
	Tue				
	Wed				
	Thu				
	Fri				
	Sat	Saturday	Saturday	Saturday	Saturday
	Sun	Sunday	Sunday	Sunday	Sunday
2	Mon				
	Tue				
	Wed				
	Thu				
	Fri				
	Sat	Saturday	Saturday	Saturday	Saturday
	Sun	Sunday	Sunday	Sunday	Sunday
3	Mon				
	Tue				
	Wed				
	Thu				
	Fri				
	Sat	Saturday	Saturday	Saturday	Saturday
	Sun	Sunday	Sunday	Sunday	Sunday
4	Mon				
	Tue				
	Wed				
	Thu				
	Fri				
	Sat	Saturday	Saturday	Saturday	Saturday
	Sun	Sunday	Sunday	Sunday	Sunday
5	Mon				
	Tue				
	Wed				
	Thu				
	Fri				
	Sat	Saturday	Saturday	Saturday	Saturday
	Sun	Sunday	Sunday	Sunday	Sunday

Performed By: ______________________________ **Date:** ______________

Reviewed By: ______________________________ **Date:** ______________

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DRUG PRODUCT FREEZER DAILY MONITORING LOG

Freezer ID/Location: ______________________________

Month/Year: ____________________ Appropriate Temperature Range: *-20°C to -10°C*

Week	Day	Date	Time	Freezer Temperature (°C)	Initials
1	Mon				
	Tue				
	Wed				
	Thu				
	Fri				
	Sat	Saturday	Saturday	Saturday	Saturday
	Sun	Sunday	Sunday	Sunday	Sunday
2	Mon				
	Tue				
	Wed				
	Thu				
	Fri				
	Sat	Saturday	Saturday	Saturday	Saturday
	Sun	Sunday	Sunday	Sunday	Sunday
3	Mon				
	Tue				
	Wed				
	Thu				
	Fri				
	Sat	Saturday	Saturday	Saturday	Saturday
	Sun	Sunday	Sunday	Sunday	Sunday
4	Mon				
	Tue				
	Wed				
	Thu				
	Fri				
	Sat	Saturday	Saturday	Saturday	Saturday
	Sun	Sunday	Sunday	Sunday	Sunday
5	Mon				
	Tue				
	Wed				
	Thu				
	Fri				
	Sat	Saturday	Saturday	Saturday	Saturday
	Sun	Sunday	Sunday	Sunday	Sunday

Performed By: ______________________________ **Date:** ______________

Reviewed By: ______________________________ **Date:** ______________

ORIGINAL COPY

07-06-11

TITLE: USE, CALIBRATION AND MAINTENANCE OF THE ANALYTICAL BALANCES	
SOP NUMBER: 4.030	**VERSION NUMBER: 1.0**
Non-Sterile and Sterile Laboratory	First Effective Date 04-25-06
Originator: Annette M. Robinson	Previous Effective Date NA
Reviewer: Barry J	Current Effective Date 03-17-08

1.0 PURPOSE

1.1 The purpose of this procedure is to outline the use, calibration and maintenance of the analytical balances.

2.0 SCOPE

2.1 This procedure applies to all personnel using the analytical balances at New England Compounding Center.

3.0 RESPONSIBILITY

3.1 The Pharmacist-in-charge shall supervise this procedure or document that another staff member has been designated to complete this task.

4.0 REFERENCES

4.1 Instruction manual(s)

4.2 Analytical balance(s)

- 4.2.1 Ohaus Adventurer Balance
- 4.2.2 Ohaus Explorer Balance
- 4.2.3 Ohaus Explorer Pro Balance
- 4.2.4 Mettler Toledo Balance

4.3 USP Current Version <41> "Weights and Balances"

4.4 USP Current Version <1251> "Weighing on an Analytical Balance"

5.0 DEFINITIONS

5.1 Tare – the deduction of the weight of a container used to calculate the weight of its contents.

5.2 Measurement Uncertainty – random plus systematic error.

5.3 Analytical Balance – an instrument used to measure mass to a very high degree of precision.

6.0 FREQUENCY

6.1 Calibration must be performed by an outside contractor every year. Town of Framingham, Weights and Measures. (1-508-532-5480)

6.2 Verification must be performed at least every six months or when the balance is moved.

6.3 The measurement uncertainty used for "accurately weighed" substances must not exceed 0.001.

6.4 The drift must be checked daily when the balance is in use.

6.4.1 The drift must not exceed ±0.2 mg. Per USP <1251>, this ±0.2 mg tolerance does not correspond to the value of 0.1% specified in USP <41> for weighing material accurately. Rather, the tolerance is purposefully tight to reveal possible drift or calibration errors.

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7.0 EQUIPMENT & SUPPLIES

7.1 NIST traceable (or equivalent) calibrated weight set

7.2 Calibrated Class I weights

7.3 Weights for drift checks

7.4 Diethyl ether, ACS Reagent Grade, Aldrich Cat. No. 47, 248-4 or equivalent

7.5 Receivers (weigh boats, weighing paper, beakers, flasks, weighing bottles, etc.)

7.6 Lint-free cloth or equivalent

7.7 Spatula or appropriate tool to transfer the sample to be weighed from the container to the receiver

7.8 Mild detergent

7.9 Scale brush

7.9 Forceps or hemostats

8.0 GENERAL INFORMATION

8.1 Allow at least twenty minutes of warm up time (thirty minutes for the Mettler Toledo balance) before calibrating the balance to give internal components sufficient time to stabilize. Analytical Class I balances require at least 2 hours of warm-up time.

8.2 Keep the operating environment as clean as possible to avoid an adverse effect on the reliability and accuracy of the unit.

8.3 Always set up the unit on a level surface in a clean, draft-free area. When using the balance in a hood or glove box, make sure the doors remain closed during weighing.

8.4 Do not install the balance near air conditioning or heating vents.

8.5 Do not install the balance near vibrating, rotating or reciprocating equipment.

8.6 Do not install the balance near magnetic fields or equipment that generates magnetic fields.

8.7 Do not disturb the balance while calibration is being performed.

8.8 The weight of the receiver plus the weight to be measured cannot exceed the limit of the balance.

8.9 It is necessary to differentiate between **calibration** and **verification**.

  8.9.1 All balances must be **calibrated** on a yearly basis by an outside contractor. A balance that is new can be **verified** for the first year and then must be calibrated by the outside contractor every year thereafter.

  8.9.2 **Calibration** may substitute for **verification**, but **verification** may not substitute for **calibration**.

9.0 PROCEDURE

9.1 Use

  9.1.1 Verify that the balance is level prior to weighing. If the balance is not level or has been moved, then follow the steps below.

    9.1.1.1 Viewing the balance from above, turn the leveling foot opposite of the location of the bubble clockwise or counterclockwise until the bubble is positioned in the center of the black ring.

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NOTE: The bubble moves toward a foot when that foot is turned clockwise, and the bubble moves away from a foot when that foot is turned counterclockwise.

9.1.1.2 Repeat step 9.1.1.1 with the other leveling foot until the bubble is positioned in the center of the black ring.

9.1.1.3 Avoid extending the leveling feet too far.

9.1.2 Ohaus Adventurer Balance

9.1.2.1 Press **>OT<** to turn the balance on. ***The drift must be checked daily when the balance is in use*** (section 9.3).

9.1.2.2 Allow the balance at least twenty minutes to warm up.

9.1.2.3 Verify the correct unit of measure is being used for weighing.

9.1.2.4 To select the appropriate measuring units, the balance must be turned off.

9.1.2.4.1 Press and hold **>OT<** until **MENU** is displayed, release, **UNITS** is displayed.

9.1.2.4.2 Press **>OT<** to enter the **UNITS** menu.

9.1.2.4.3 To turn a unit of measurement on or off, press **>OT<** to select the unit and press **Mode Off** to turn the unit on or off.

9.1.2.4.4 You must continue until **END** appears.

9.1.2.4.5 To save the settings, select **END** and press **>OT<**.

9.1.2.4.6 To exit the menu, repeatedly press **Mode Off** until **MENU END** is displayed, then press **>OT<**.

9.1.2.5 Turn the balance on and make sure the balance is in weighing mode.

9.1.2.6 To tare the balance, momentarily press **>OT<**.

9.1.2.7 Place items to be weighed on the balance pan, wait for the value to stabilize and read the weight on the display. The stability indicator * appears when the reading is stable.

9.1.2.8 When using a container to weigh items, place the empty container on the balance pan, wait for the value to stabilize, then momentarily press **>OT<**. When the display reads zero, add the item to the container, wait for the value to stabilize and read the weight on the display.

9.1.2.9 Double-check the accuracy of weighing against the compounding formula before proceeding with the compounding procedure.

9.1.2.10 Remove any chemical or material that has spilled on the pan or under the pan with a damp low-lint wipe or a scale brush.

9.1.2.11 Turn off the balance by pressing and holding **Mode Off** until the display indicates **OFF**.

9.1.3 Ohaus Explorer Balance

9.1.3.1 Press the **ON/OFF** button to turn the balance on. ***The drift must be checked daily when the balance is in use*** (section 9.3).

9.1.3.2 Allow the balance at least twenty minutes to warm up.

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9.1.3.3 Verify the correct unit of measure is being used for weighing.

9.1.3.4 To select the appropriate measuring units, the desired unit must be enabled.

9.1.3.4.1 Press the **Setup** button, **CAL** is displayed.

9.1.3.4.2 Press the left or right arrow buttons until **UNITS** is displayed.

9.1.3.4.3 Press the **Enter** button to continue.

9.1.3.4.4 Press the left or right arrow buttons until the desired measuring unit is displayed.

9.1.3.4.5 Press the **Enter** button to continue.

9.1.3.4.6 Press the up or down arrow buttons and select either **ON** or **OFF**.

9.1.3.4.7 Press the enter button to save the settings.

9.1.3.4.8 Press the left or right arrow buttons to select the next item or **EXIT**.

9.1.3.4.9 Press the **Enter** button to continue.

9.1.3.5 To tare the balance, press #.

9.1.3.6 To select the appropriate measuring unit, press the **Units** button.

9.1.3.7 Press the left or right arrow buttons to select the desired unit.

9.1.3.8 Press the **Enter** button.

9.1.3.9 Place items to be weighed on the balance pan, and wait for the stability indicator to appear before reading the weight on the display.

9.1.3.10 When using a container to weigh items, place the empty container on the balance pan, wait for the value to stabilize, then press # to tare the balance. When the display reads zero, add the item to the container, wait for the value to stabilize and read the weight on the display.

9.1.3.11 Double-check the accuracy of weighing against the compounding formula before proceeding with the compounding procedure.

9.1.3.12 Remove any chemical or material that has spilled on the pan or under the pan with a damp low-lint wipe or a scale brush.

9.1.3.13 Turn off the balance by pressing the **ON/OFF** button.

9.1.4 Ohaus Explorer Pro Balance

9.1.4.1 Press the **ON/OFF** button to turn the balance on. ***The drift must be checked daily when the balance is in use*** (section 9.3).

9.1.4.2 Allow the balance at least twenty minutes to warm up.

9.1.4.3 Verify the correct unit of measure is being used for weighing.

9.1.4.4 To select the appropriate measuring units, press the **Menu** button and select **Units**.

9.1.4.5 Scroll through the menu using the up or down arrow button and turn on/off the desired measuring units.

9.1.4.6 To tare the balance, press the **>OT<** button.

9.1.4.7 Place items to be weighed on the balance pan, and wait for the stability indicator (*) to appear before reading the weight on the display.

9.1.4.8 When using a container to weigh items, place the empty container on the balance pan, wait for the value to stabilize, then press the **>OT<** button to tare the balance. When the display reads zero, add the item to the container, wait for the value to stabilize and read the weight on the display.

9.1.4.9 Double-check the accuracy of weighing against the compounding formula before proceeding with the compounding procedure.

9.1.4.10 Remove any chemical or material that has spilled on the pan or under the pan with a damp low-lint wipe or a scale brush.

9.1.4.11 Turn off the balance by pressing the **ON/OFF** button.

9.1.5 Mettler Toledo Balances

9.1.5.1 Press the **ON** button to turn the balance on. ***The drift must be checked daily when the balance is in use*** (section 9.3).

9.1.5.2 Allow the balance at least thirty minutes to warm up.

9.1.5.3 Verify the correct unit of measure is being used for weighing.

9.1.5.4 To select the appropriate measuring units, the balance must be in weigh mode.

9.1.5.5 Press and hold the **Cal/Menu** button until **MENU** is displayed.

9.1.5.6 Scroll through the menu until **UNIT 1** is displayed (9th menu option) and select the desired measuring units.

9.1.5.7 Press and hold the **Cal/Menu** button until **STORED** is displayed.

9.1.5.8 To tare the balance, press the **>OT<** button.

9.1.5.9 Place items to be weighed on the balance pan, and wait for the stability indicator (°) to disappear before reading the weight on the display.

9.1.5.10 When using a container to weigh items, place the empty container on the balance pan, wait for the value to stabilize, then press the **>OT<** button to tare the balance. When the display reads zero, add the item to the container, wait for the value to stabilize and read the weight on the display.

9.1.5.11 Double-check the accuracy of weighing against the compounding formula before proceeding with the compounding procedure.

9.1.5.12 Remove any chemical or material that has spilled on the pan or under the pan with a damp low-lint wipe or a scale brush.

9.1.5.13 Turn off the balance by pressing the **OFF** button.

9.2 Verification

9.2.1 Turn on the balance.

9.2.2 Verify that the balance is level prior to weighing. If the balance is not level or has been moved, then follow the steps in section 9.1.1.

9.2.3 Using forceps or hemostats, place a calibrated 10 mg weight on the scale. Do not touch the calibrated weights with exposed skin.

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9.2.4 Record the actual weight of the standard and the reading on the display on Attachment 1.

9.2.5 Using forceps or hemostats, remove the weight from the balance.

9.2.6 Repeat steps 9.2.3 through 9.2.5 for the remaining weights listed under the "Class I Calibrated Mass" column on Attachment 1.

9.2.7 Repeat steps 9.2.3 through 9.2.5 using a calibrated 100 mg weight for total of ten readings.

9.2.8 Calculate and record the standard deviation on Attachment 1.

9.2.8.1 Standard Deviation (σ) = $\sqrt{\frac{\Sigma(x-\bar{x})^2}{n-1}}$

X = value of individual reading (Reading 1, Reading 2...Reading 10)

X bar = average of the 10 readings

n = number of readings (10)

9.2.9 Calculate and record the measurement uncertainty on Attachment 1.

9.2.9.1 Measurement Uncertainty = 3*(standard deviation) / weight of standard

9.2.10 Repeat steps 9.2.7 through 9.2.9 using a 50 g weight for a total of ten readings.

9.2.11 If the measurement uncertainty is $\leq$ 0.001, the balance is considered within calibration.

9.2.12 If the measurement uncertainty is > 0.001, remove the balance from service. Verify that the weights are correct by cleaning and checking the weight on a different balance. If the weights appear to be compromised, obtain another set of weights and repeat the above steps. If all calibration weights meet the specification, then the balance can be returned to service. If the weights were not compromised, then call the manufacturer or qualified vendor for recommended corrective action.

9.3 Measurement of Drift for Analytical Balances

9.3.1 Tolerance

9.3.1.1 Calibrated weights need not be used for drift checks.

9.3.1.2 Using forceps or hemostats, place a 1 g weight on the balance pan. Do not touch the weights. When the stability indicator is displayed, read the result.

9.3.1.3 Record the weight on Attachment 2.

9.3.1.4 Remove the weight from the balance with forceps or hemostats. Weigh the weight again for a total of three times on three consecutive working days.

9.3.1.5 After 9 measurements are obtained, calculate the average.

9.3.1.6 The tolerance for drift measurements is established as the average weight ± 0.2 mg.

9.3.1.7 Record the tolerance on Attachment 2.

9.3.1.8 The tolerance should be re-determined if one of the following occurs:

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9.3.1.8.1 The weight set or individual weight has changed.

9.3.1.8.2 The location of the balance has changed.

9.3.1.9 If the tolerance is to be re-determined, document the reason for re-determination in the comments section on Attachment 2.

9.3.1.10 These are to preformed only initially, for new equipment or if balances are moved.

9.3.2 Drift

9.3.2.1 Verify that the balance is level prior to weighing. If the balance is not level or has been moved, then follow the steps in section 9.1.1.

9.3.2.2 Using forceps or hemostats, place a 1 g weight on the balance pan. Do not touch the weights. When the stability indicator is displayed, read the result.

9.3.2.3 Record the weight daily on Attachment 3.

9.3.2.4 If the measured weight does not meet the tolerances, clean the weight with diethyl ether and a lint-free cloth. Reweigh the weights. If the measured weights still do not meet the requirements, perform balance verification. If the balance verification is successful, place the balance back into service and establish a new tolerance for the drift check weights.

9.4 Calibration

9.4.1 All balances must be calibrated on a yearly basis by an outside contractor. A balance that is new can be verified for the first year and then must be calibrated by the outside contractor every year thereafter.

9.5 Cleaning/Maintenance

9.5.1 Cleaning should be performed after spills occur or if the balance is visibly dirty.

9.5.2 Clean the balance with a mild detergent using a soft cloth or a low-lint wipe.

9.5.3 Keep calibration masses in a safe, dry place.

10.0 ATTACHMENTS

10.1 Attachment 1 – Verification Log for Analytical Balances

10.2 Attachment 2 – Drift Tolerance for Analytical Balances

10.3 Attachment 3 – Measurement of Drift for Analytical Balances

03-17-08

11.0 HISTORY

Version Number	Date Effective	Description of Change	Change Request Number
1.0	03-17-08	New SOP	CR06017

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amx 03-17-08

VERIFICATION LOG FOR ANALYTICAL BALANCES (BI-ANNUAL)

Verification Date: ____________________

Balance ID: ____________________ **Balance Cal. Due:** ____________________

Weight Set ID: ____________________ **Weight Set Cal. Due:** ____________________

Class I Calibrated Mass	Weight Standard Range (g) *(calibrated mass ± 0.1%)*	Balance Reading (g)	Pass/Fail
10mg			☐ Pass ☐ Fail
20mg			☐ Pass ☐ Fail
50mg			☐ Pass ☐ Fail
100mg			☐ Pass ☐ Fail
200mg			☐ Pass ☐ Fail
500mg			☐ Pass ☐ Fail
1g			☐ Pass ☐ Fail
2g			☐ Pass ☐ Fail
5g			☐ Pass ☐ Fail
10g			☐ Pass ☐ Fail
20g			☐ Pass ☐ Fail
50g			☐ Pass ☐ Fail
100g			☐ Pass ☐ Fail
120g			☐ Pass ☐ Fail
150g			☐ Pass ☐ Fail
170g			☐ Pass ☐ Fail
200g			☐ Pass ☐ Fail
210g			☐ Pass ☐ Fail

Standard Weight	Weight of Standard (g)	Reading 1 (g)	Reading 2 (g)	Reading 3 (g)	Reading 4 (g)	Reading 5 (g)
100mg						
50g						
Standard Weight	**Reading 6 (g)**	**Reading 7 (g)**	**Reading 8 (g)**	**Reading 9 (g)**	**Reading 10 (g)**	**Standard Deviation¹ (g)**
100mg						
50g						

Standard Weight	Standard Deviation (g)	Weight of Standard (g)	Measurement Uncertainty²	Pass/Fail (pass if ≤ 0.001)
100mg				☐ Pass ☐ Fail
50g				☐ Pass ☐ Fail

[1] Standard Deviation = $\sqrt{\frac{\Sigma(x-\bar{x})^2}{n-1}}$

[2] Measurement Uncertainty = 3*(standard deviation) / weight of standard

Performed By: ______________________________ **Date:** ____________________

Reviewed By: ______________________________ **Date:** ____________________

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5-17-08

DRIFT TOLERANCE FOR ANALYTICAL BALANCES

Balance ID: ____________ Balance Cal. Due: ____________ Weight Set ID: ____________

Nominal Weight	Date	Triplicate Measurements (g)	Average (g)	Tolerance (average ± 0.2mg)

Comments:

Performed By: ____________ Date: ____________

Reviewed By: ____________ Date: ____________

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MEASUREMENT OF DRIFT FOR ANALYTICAL BALANCES (DAILY)

Month/Year: ______________________ **Balance ID:** ______________________

Balance Cal. Due: ______________________ **Weight Set ID:** ______________________

Date	Nominal Mass Value	Balance Reading (g)	Tolerance Range (g)	Pass/Fail	Initials
	1 gram			☐ Pass ☐ Fail	
	1 gram			☐ Pass ☐ Fail	
	1 gram			☐ Pass ☐ Fail	
	1 gram			☐ Pass ☐ Fail	
	1 gram			☐ Pass ☐ Fail	
	1 gram			☐ Pass ☐ Fail	
	1 gram			☐ Pass ☐ Fail	
	1 gram			☐ Pass ☐ Fail	
	1 gram			☐ Pass ☐ Fail	
	1 gram			☐ Pass ☐ Fail	
	1 gram			☐ Pass ☐ Fail	
	1 gram			☐ Pass ☐ Fail	
	1 gram			☐ Pass ☐ Fail	
	1 gram			☐ Pass ☐ Fail	
	1 gram			☐ Pass ☐ Fail	
	1 gram			☐ Pass ☐ Fail	
	1 gram			☐ Pass ☐ Fail	
	1 gram			☐ Pass ☐ Fail	
	1 gram			☐ Pass ☐ Fail	
	1 gram			☐ Pass ☐ Fail	
	1 gram			☐ Pass ☐ Fail	
	1 gram			☐ Pass ☐ Fail	
	1 gram			☐ Pass ☐ Fail	
	1 gram			☐ Pass ☐ Fail	
	1 gram			☐ Pass ☐ Fail	

Comments:

____

____

____

Reviewed By: ______________________________ **Date:** ______________

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mmk 03-17-08

TITLE: USE, VERIFICATION AND MAINTENANCE OF THE DRY-HEAT OVEN
SOP NUMBER: 4.050 **VERSION NUMBER: 5.0**
Sterile Laboratory Effective Date 07-08-11
Originator:
Reviewer:

1.0 PURPOSE

1.1 The purpose of this procedure is to outline the use, verification and maintenance of the dry-heat oven.

2.0 SCOPE

2.1 This procedure applies to personnel using the dry-heat oven at New England Compounding Center.

3.0 RESPONSIBILITY

3.1 Personnel involved in dry-heat sterilization or depyrogenation should be thoroughly familiar with the sterilization process and the equipment involved.

3.2 Personnel should:

- 3.2.1 Establish that the equipment is capable of operating within the required parameters.
- 3.2.2 Establish that dry-heat sterilization is appropriate for the products to be sterilized (i.e. beakers, spatulas, spoons).
- 3.2.3 Conduct replicate cycles employing actual or simulated product and demonstrating the success of the procedure, whether sterilizing or depyrogenating.
- 3.2.4 Monitor the process during routine operation.
- 3.2.5 Complete the documentation "Depyrogenation/Dry Heat Sterilization Cycle Batch Log Sheet (Attachment 1)."

4.0 REFERENCES

4.1 USP Current Version <797> "Pharmaceutical Compounding – Sterile Preparations"

4.2 PDA Technical Report No. 3

4.3 SOP 1.040 "Log of Maintenance and Cleaning (L-MAC)"

4.4 SOP 8.010 "Sterilization and Depyrogenation"

4.5 Equipment Instruction manuals

5.0 DEFINITIONS

5.1 Depyrogenation – Process used to destroy or remove pyrogen (endotoxins)

5.2 L-MAC – Log of Maintenance and Cleaning

6.0 FREQUENCY

6.1 Preventative Maintenance/Calibration to be done yearly (outside vendor).

7.0 EQUIPMENT & SUPPLIES

7.1 Dry-heat oven capable of achieving and maintaining an appropriate temperature for sterilization and, if applicable, depyrogenation (260°C)

COPY

7.2 Calibrated chart recorder

7.3 70% isopropyl alcohol (IPA)

8.0 GENERAL INFORMATION

8.1 In order to achieve sterilization, the product must reach and maintain a temperature of 170°C for at least two hours.

8.2 Glass and metal devices may be covered tightly with aluminum foil, and then exposed to dry heat in an oven at a mean temperature of 260°C for at least two hours to achieve sterility and depyrogenation, according to USP <797>. (Document on Attachment 1 "Depyrogenation/Dry Heat Sterilization Cycle Batch Log Sheet")

8.3 When not in use, the oven shall be turned off.

9.0 PROCEDURE

9.1 USE

9.1.1 **Do not depend upon the oven buttons to set the temperature..**

9.1.2 To achieve depyrogenation, prepare the glass or metal device with 2 layers of aluminum foil covering the opening, and then expose the device to dry heat in the VWR oven at a mean temperature of 260°C..

9.1.3 If sterilizing or depyrogenating more than one item, arrange the items evenly throughout the oven chamber, providing ample space for heated airflow between them. (Document on Attachment 1 "Depyrogenation/Dry Heat Sterilization Cycle Batch Log Sheet")

9.1.4 Continue the sterilization process until the complete time has elapsed.

9.1.5 Turn off the heat and allow the oven to cool. Open the door and remove the items.

9.1.6 Clean the oven and close the door.

9.2 Preventative Maintenance(PM)/Calibration

9.2.1 Outside Vendor - Alert Scientific Incorporated (1-800-872-2028).

9.2.1.1 According to vendor specifications.

9.3 Operation of the VWR Air Flow Oven Model 1685 with Watlow 981 Controller for depyrogenation purposes.

9.3.1 Turn the oven on with the main power (**I/O**) switch.

9.3.2 Verify lower display is **OFF**. If lower display shows a temperature, use the up/down keys to set the lower display to **OFF**.

9.3.3 Press the **Hold/Run** key once. (The **RUN LED** begins flashing, and the lower display flashes **FILE** and asks what **FILE** is to be run).

9.3.4 Use the up/down keys to select the file number in the upper display.

9.3.5 Choose **FILE 1**.

9.3.6 Press **Mode** key and the lower displays flashes **STEP** and asks what **STEP** is to be run.

9.3.7 Use the up/down keys to select the **STEP** number in the upper display.

9.3.8 Choose **STEP 1**.

9.3.9 Press the **Hold/Run** key once. The profile begins and the **RUN LED** is lit.

9.3.10 If you decide not to run a profile, press the **Display** key to exit the pre-run menu.

9.3.11 Turn the oven off with the main power (**I/O**) switch for a minimum of 2 minutes. After, two minutes have passed, turn the oven on and repeat steps 9.3.2 to 9.3.11.

9.4 Cleaning

9.4.1 The interior and exterior of the oven can be kept clean by periodically wiping with a cloth dampened with purified water or 70% IPA inside and out. (Document on the L-MAC).

9.5 Perform maintenance as required per equipment manual.

10.0 ATTACHMENTS

10.1 Attachment 1 – Depyrogenation/Dry Heat Sterilization Cycle Batch Log Sheet

11.0 HISTORY

Version Number	Date Effective	Description of Change	Change Request Number
1.0	03/28/06	New SOP	CR06019
2.0	04/18/06	Clarified section 8.2. Deleted "The temperature of each individual product must be monitored" from section 9.1.5. Added section 9.2.3 and section 9.3.	CR06061
3.0	10/25/07	Minor Updates	CR07010
4.0	09/29/08	Added Depyrogenation/Dry heat sterilization cycle batch log sheet/ Took out verification sheet	CR08019
5.0	07/07/11	Updated to match the process/minor corrections	CR11006

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DEPYROGENATION / DRY HEAT STERILIZATION CYCLE BATCH LOG SHEET

ATTACHMENT 1

BATCH NUMBER: ____________________ DATE: __________ INITIALS: __________

Number Of Items	Type of Package		Contents		
	☐ Beaker ☐ Spatula/Spoon ☐ Homogenizer ☐ Catheter ☐ Misc: ____________	☐ Mortar/Pestle (S) ☐ Mortar/Pestle (L) ☐ Forceps/Scissors ☐ AGFU	☐ 40 mL ☐ 80 mL ☐ 200 mL ☐ 300 mL ☐ 500 mL	☐ 1 L ☐ 1.4 L ☐ 1.8 L ☐ 2 L ☐ 2.5 L	☐ 2.8 L ☐ 4 L ☐ 5 L ☐ 10 L ☐ 15 L
	☐ Beaker ☐ Spatula/Spoon ☐ Homogenizer ☐ Catheter ☐ Misc: ____________	☐ Mortar/Pestle (S) ☐ Mortar/Pestle (L) ☐ Forceps/Scissors ☐ AGFU	☐ 40 mL ☐ 80 mL ☐ 200 mL ☐ 300 mL ☐ 500 mL	☐ 1 L ☐ 1.4 L ☐ 1.8 L ☐ 2 L ☐ 2.5 L	☐ 2.8 L ☐ 4 L ☐ 5 L ☐ 10 L ☐ 15 L
	☐ Beaker ☐ Spatula/Spoon ☐ Homogenizer ☐ Catheter ☐ Misc: ____________	☐ Mortar/Pestle (S) ☐ Mortar/Pestle (L) ☐ Forceps/Scissors ☐ AGFU	☐ 40 mL ☐ 80 mL ☐ 200 mL ☐ 300 mL ☐ 500 mL	☐ 1 L ☐ 1.4 L ☐ 1.8 L ☐ 2 L ☐ 2.5 L	☐ 2.8 L ☐ 4 L ☐ 5 L ☐ 10 L ☐ 15 L
	☐ Beaker ☐ Spatula/Spoon ☐ Homogenizer ☐ Catheter ☐ Misc: ____________	☐ Mortar/Pestle (S) ☐ Mortar/Pestle (L) ☐ Forceps/Scissors ☐ AGFU	☐ 40 mL ☐ 80 mL ☐ 200 mL ☐ 300 mL ☐ 500 mL	☐ 1 L ☐ 1.4 L ☐ 1.8 L ☐ 2 L ☐ 2.5 L	☐ 2.8 L ☐ 4 L ☐ 5 L ☐ 10 L ☐ 15 L
	☐ Beaker ☐ Spatula/Spoon ☐ Homogenizer ☐ Catheter ☐ Misc: ____________	☐ Mortar/Pestle (S) ☐ Mortar/Pestle (L) ☐ Forceps/Scissors ☐ AGFU	☐ 40 mL ☐ 80 mL ☐ 200 mL ☐ 300 mL ☐ 500 mL	☐ 1 L ☐ 1.4 L ☐ 1.8 L ☐ 2 L ☐ 2.5 L	☐ 2.8 L ☐ 4 L ☐ 5 L ☐ 10 L ☐ 15 L
	☐ Beaker ☐ Spatula/Spoon ☐ Homogenizer ☐ Catheter ☐ Misc: ____________	☐ Mortar/Pestle (S) ☐ Mortar/Pestle (L) ☐ Forceps/Scissors ☐ AGFU	☐ 40 mL ☐ 80 mL ☐ 200 mL ☐ 300 mL ☐ 500 mL	☐ 1 L ☐ 1.4 L ☐ 1.8 L ☐ 2 L ☐ 2.5 L	☐ 2.8 L ☐ 4 L ☐ 5 L ☐ 10 L ☐ 15 L
	☐ Beaker ☐ Spatula/Spoon ☐ Homogenizer ☐ Catheter ☐ Misc: ____________	☐ Mortar/Pestle (S) ☐ Mortar/Pestle (L) ☐ Forceps/Scissors ☐ AGFU	☐ 40 mL ☐ 80 mL ☐ 200 mL ☐ 300 mL ☐ 500 mL	☐ 1 L ☐ 1.4 L ☐ 1.8 L ☐ 2 L ☐ 2.5 L	☐ 2.8 L ☐ 4 L ☐ 5 L ☐ 10 L ☐ 15 L
	☐ Beaker ☐ Spatula/Spoon ☐ Homogenizer ☐ Catheter ☐ Misc: ____________	☐ Mortar/Pestle (S) ☐ Mortar/Pestle (L) ☐ Forceps/Scissors ☐ AGFU	☐ 40 mL ☐ 80 mL ☐ 200 mL ☐ 300 mL ☐ 500 mL	☐ 1 L ☐ 1.4 L ☐ 1.8 L ☐ 2 L ☐ 2.5 L	☐ 2.8 L ☐ 4 L ☐ 5 L ☐ 10 L ☐ 15 L

Indicator Included: ☐Yes ☐No	Labels Made: ☐Yes ☐No	Chart Recorder Confirm: ☐Yes ☐No

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TITLE: USE, VERIFICATION AND MAINTENANCE OF THE AUTOCLAVE	
SOP NUMBER: 4.060	**VERSION NUMBER: 4.0**
Sterile Laboratory	Effective Date 07/07/11
Originator:	
Reviewer:	

1.0 PURPOSE

1.1 The purpose of this procedure is to outline the use, verification and maintenance of the autoclave.

2.0 SCOPE

2.1 This procedure applies to all personnel using the autoclaves at New England Compounding Center.

3.0 RESPONSIBILITY

3.1 Personnel involved in terminal sterilization via the use of an autoclave should be thoroughly familiar with the sterilization process and the equipment involved. Personnel are responsible for:

3.1.1. Establishing that the equipment is capable of operating within the required parameters.

3.1.2 Establishing that steam sterilization is appropriate for the products to be sterilized.

3.1.3 Conducting replicate cycles employing actual or simulated product and demonstrating the success of the procedure.

3.1.4 Monitoring the process during routine operation.

3.1.5 Completing the documentation.

4.0 REFERENCE

4.1 Instruction manual

5.0 DEFINITION

N/A

6.0 FREQUENCY

N/A

7.0 EQUIPMENT & SUPPLIES

7.1 Autoclave capable of achieving and maintaining a minimum temperature of 121°C and a minimum pressure of 15psi with the ability to chart and print temperature, pressure and time increments throughout the cycle.

7.2 Instruction manual

7.3 Non-abrasive chamber cleaner

7.4 Appropriate chemical indicator.

8.0 GENERAL INFORMATION

8.1 Use an appropriate chemical indicator that melts at 121.1°C. After running for 15 minutes at temperature, move indicator to the "safe" zone.

8.2 Water used in the autoclave should be free from minerals and deposits that may build up inside the autoclave on the steel surface.

8.3 The autoclave should be installed in conformance with the following parameters:

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8.3.1 The unit must be placed on a level, heat and water resistant surface.

8.3.2 Allow at least 3 inches between the unit and walls on the sides and back for air circulation, and allow at least 8 inches between the top of the unit and any objects overhead.

8.3.3 If the unit operates continuously, it must be located in an area where steam emissions will not damage equipment or materials.

8.4 Operational Programs

8.4.1 Unwrapped goods (3 minutes at 135°C) – for unwrapped instruments and items made of metal, glass or plastic.

8.4.2 Wrapped goods (10 minutes at 135°C) – for wrapped packs of clothes, bandages, pads, fabrics, rubber tubing and metal instruments (15 minutes drying time).

8.4.3 Liquids (15 minutes at 121°C) – for distilled water, media solutions and other liquid prepared in closed bottles or flasks.

8.4.4 Packs (30 minutes at 121°C) – for packs of instruments and towels and other packed goods.

9.0 PROCEDURES

9.1 Use

9.1.1 Push the power switch under the right front corner of the sterilizer to the **on** position.

9.1.2 Remove the cover to the water reservoir and fill the reservoir with mineral free water until the water level reaches the bottom of the fill line in the reservoir.

9.1.2.1 Do not overfill.

9.1.2.2 When the reservoir runs low on water, the low level sensor will alert the user of the low water condition.

9.1.2.3 The VWR reservoir holds approximately 4 liters of water. The Tuttnauer reservoir holds spproximately 6 liters of water.

9.1.3 The load to be sterilized must be prepared accordingly.

9.1.3.1 Clean items thoroughly before placing them in the sterilizer.

9.1.3.2 Unwrapped goods should only be processed on trays. Do not place items on the rack or the bottom of the sterilizer.

9.1.3.3 Liquids must not exceed 75% of the capacity of the container. Use self-venting caps.

9.1.3.4 Open all hinged instruments.

9.1.3.5 Remove the covers from empty containers. Stand the containers and covers on their sides.

9.1.3.6 Turn curved vessels upside down so no water will collect in the vessel.

9.1.3.7 Place all sharp instruments so that they do not touch during sterilization. Cotton or gauze may be used to isolate and protect the sharp edges and smaller instruments.

9.1.3.8 Disassemble syringes if possible. Do not plug syringes or needles.

9.1.3.9 Do not overload the trays as it may result in inadequate sterilization.

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9.2 Load the chamber.

9.2.1 Do not exceed the specified loads for a cycle.

9.2.1.1 Unwrapped goods – Items to be sterilized unwrapped should be distributed in a single layer on the bottom of a lined, perforated tray. **Do not overload tray**; allow space around instruments for steam circulation.

9.2.1.2 Metal and glass containers should be placed upside down on a perforated tray. Make sure containers are placed so that they will drain sufficiently to ensure sterilization.

9.2.1.3 Wrapped goods – Items to be sterilized wrapped should be placed loose in the bottom of a lined, perforated tray. Additional layers of instruments may be added, separated by fabric. **Do not overload the tray**; steam must be able to penetrate through the entire tray. Wrap the tray in 2 to 4 layers of muslin or other appropriate wrapping material. Seal with autoclave tape.

9.2.1.4 Packs – no more than 2.8 pounds and no more than 14 towels.

9.2.1.5 Liquids – flasks filled no more than 75% full.

9.2.1.6 Do not allow packs or wrappings to touch chamber walls or one another.

9.2.1.7 Do not stack trays on top of one another.

9.2.2 A biological indicator is included with each autoclave cycle.

9.2.3 Close the chamber door.

9.2.4 Select the appropriate processing cycle.

9.2.5 Set the drying time if needed (for pack, wrapped and unwrapped cycles).

9.2.6 Press the **Start Cycle** button.

9.2.7 Once the cycle is complete, attach all printouts to the corresponding formula worksheet.

9.2.8 Filled-Chamber Verification

9.2.8.1 Place an appropriate chemical indicator in the middle of the load, close and tighten the autoclave door, select the proper cycle and press start.

9.2.8.2 Once the cycle is complete, remove the indicator.

9.3 Cleaning/Maintenance

9.3.1 **Daily**

9.3.1.1 Clean external surfaces daily with 70% IPA (sterile)

9.3.1.2 The door gasket and the mating surface should be wiped clean each day with a clean damp cloth.

9.3.1.3 The gasket should be examined for cracks and damage that could result in a poor pressure seal.

9.3.1.4 Clean the chamber at the end of the day with damp towel with or without mild detergent.

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9.3.1.5 **Note: Do not use wire brushes, abrasive or bleaching agents in the chamber (i.e. steel wool, scouring powder, bleach, etc.) as damage to the chamber and other components could result.**

9.4.1 **Weekly**

9.4.1.1 Cleaning the Reservoir

9.4.1.2 Mix the appropriate amount of autoclave cleaner with the appropriate amount of distilled water for each individual autoclave. For extra cleaning power, solution may be increased and may require two cleaning cycles. For best results always use distilled water.

9.4.1.3 Drain reservoir and fill with cleaning solution from Step 9.4.1.2.

9.4.1.4 Run one liquid cycle in a normal manner. (Instruments should not be sterilized while cleaning autoclave).

9.4.1.5 Drain cleaning solution from autoclave and reservoir. Rinse thoroughly until water runs clear. Fill reservoir again and run one wrapped cycle.

9.4.1.6 Drain rinse solution; remove trays and tray rest, wipe out inside of chamber and tray rest.

9.4.1.6 Wipe all residues from the surfaces with a dampened, lint free cloth.

9.4.1.7 Add sterile water and autoclave is ready for use.

9.5.1 **Yearly.**

9.5.1.1 Preventative Maintenance (PM)/ Calibration - Outside vendor – Alert Scientific Incorporation – 1-800-872-2028

9.5.1.2 According to vendor specifications

9.6 Sterilization Cycle Printouts/Records

9.6.1 Prior to each sterilization cycle, the batch number should be created. All materials in the sterilization cycle must be documented on Attachment 1.

9.6.2 Autoclave printout should be initialed and stapled to batch record on Attachment 1.

9.6.3 Stickers should be made with a time stamp prior to completion of the cycle and bags labeled after completion.

9.6.4 All batch records are to be kept in binders in clean room.

9.6.5 At the end of the month, they get filed in Quality Control binder.

10.0 **ATTACHMENTS**

11.0 Attachment 1 – Clean Room Autoclave Batch log Sheet

12.0 **HISTORY**

Version Number	Date Effective	Description of Change	Change Request Number
1.0	03-01-06	New SOP	CR06020
2.0	02-28-08	Added parameters temperatures, minor updates and changes	CR07024
3.0	08-14-08	Take out Attachment 1 time in and time out stamp	CR08016
4.0	07-07-11	Took out use of L-MACS,	CR11005

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TITLE: USE, VERIFICATION AND MAINTENANCE OF THE AUTOCLAVE

SOP NUMBER: 4.060 **VERSION NUMBER: 4.0**

CLEAN ROOM AUTOCLAVE BATCH LOG SHEET - Attachment 1

AUTOCLAVE/BATCH NUMBER: ______________________ DATE: __________

Number of Packages	Type of Package	Contents	
	☐ Bag, Small ☐ Bag, Medium ☐ Bag, Large ☐ Liquid ☐ Other: __________	☐ Vial, 2ML (Amber / Clear) ☐ Vial, 5ML (Amber / Clear) ☐ Vial, 10ML (Amber / Clear) ☐ Vial, 30ML ☐ Weights	☐ Spin Bar ☐ Stoppers, 13mm ☐ Stoppers, 20mm ☐ Other: ______
	☐ Bag, Small ☐ Bag, Medium ☐ Bag, Large ☐ Liquid ☐ Other: __________	☐ Vial, 2ML (Amber / Clear) ☐ Vial, 5ML (Amber / Clear) ☐ Vial, 10ML (Amber / Clear) ☐ Vial, 30ML ☐ Weights	☐ Spin Bar ☐ Stoppers, 13mm ☐ Stoppers, 20mm ☐ Other: ______
	☐ Bag, Small ☐ Bag, Medium ☐ Bag, Large ☐ Liquid ☐ Other: __________	☐ Vial, 2ML (Amber / Clear) ☐ Vial, 5ML (Amber / Clear) ☐ Vial, 10ML (Amber / Clear) ☐ Vial, 30ML ☐ Weights	☐ Spin Bar ☐ Stoppers, 13mm ☐ Stoppers, 20mm ☐ Other: ______
	☐ Bag, Small ☐ Bag, Medium ☐ Bag, Large ☐ Liquid ☐ Other: __________	☐ Vial, 2ML (Amber / Clear) ☐ Vial, 5ML (Amber / Clear) ☐ Vial, 10ML (Amber / Clear) ☐ Vial, 30ML ☐ Weights	☐ Spin Bar ☐ Stoppers, 13mm ☐ Stoppers, 20mm ☐ Other: ______
	☐ Bag, Small ☐ Bag, Medium ☐ Bag, Large ☐ Liquid ☐ Other: __________	☐ Vial, 2ML (Amber / Clear) ☐ Vial, 5ML (Amber / Clear) ☐ Vial, 10ML (Amber / Clear) ☐ Vial, 30ML ☐ Weights	☐ Spin Bar ☐ Stoppers, 13mm ☐ Stoppers, 20mm ☐ Other: ______
	☐ Bag, Small ☐ Bag, Medium ☐ Bag, Large ☐ Liquid ☐ Other: __________	☐ Vial, 2ML (Amber / Clear) ☐ Vial, 5ML (Amber / Clear) ☐ Vial, 10ML (Amber / Clear) ☐ Vial, 30ML ☐ Weights	☐ Spin Bar ☐ Stoppers, 13mm ☐ Stoppers, 20mm ☐ Other: ______
	☐ Bag, Small ☐ Bag, Medium ☐ Bag, Large ☐ Liquid ☐ Other: __________	☐ Vial, 2ML (Amber / Clear) ☐ Vial, 5ML (Amber / Clear) ☐ Vial, 10ML (Amber / Clear) ☐ Vial, 30ML ☐ Weights	☐ Spin Bar ☐ Stoppers, 13mm ☐ Stoppers, 20mm ☐ Other: ______
	☐ Bag, Small ☐ Bag, Medium ☐ Bag, Large ☐ Liquid ☐ Other: __________	☐ Vial, 2ML (Amber / Clear) ☐ Vial, 5ML (Amber / Clear) ☐ Vial, 10ML (Amber / Clear) ☐ Vial, 30ML ☐ Weights	☐ Spin Bar ☐ Stoppers, 13mm ☐ Stoppers, 20mm ☐ Other: ______
	☐ Bag, Small ☐ Bag, Medium ☐ Bag, Large ☐ Liquid ☐ Other: __________	☐ Vial, 2ML (Amber / Clear) ☐ Vial, 5ML (Amber / Clear) ☐ Vial, 10ML (Amber / Clear) ☐ Vial, 30ML ☐ Weights	☐ Spin Bar ☐ Stoppers, 13mm ☐ Stoppers, 20mm ☐ Other: ______
Type of Cycle:	☐ *Wrapped* (10 minutes at 135 °C)	☐ *Liquid* (15 minutes at 121 °C)	☐ *Other* ________
Cycle Confirmed By Chemical Indicator		☐ Yes ☐ No	
Cycle Confirmed By Print Out:		☐ Yes ☐ No	Initials:

TITLE: USE, CALIBRATION AND MAINTENANCE OF THE INCUBATOR	
SOP NUMBER: 4.070	**VERSION NUMBER: 3.0**
Sterile Laboratory	Effective Date 08-08-08
Originator:	
Reviewer:	

1.0 PURPOSE

1.1 The purpose of this procedure is to outline the use calibration and maintenance of the incubator.

2.0 SCOPE

2.1 This procedure applies to all personnel who use the incubator at New England Compounding Center.

3.0 RESPONSIBILITY

3.1 The Pharmacist-in-charge shall supervise this procedure and document that all personnel will comply with this procedure.

4.0 REFERENCES

4.1 Instruction manual

4.2 SOP - 1.040 "Log of Maintenance and Cleaning (L-MAC)"

5.0 DEFINITIONS

5.1 (L-MAC) – Log of Maintenance and Cleaning

6.0 FREQUENCY

6.1 Monitoring to be completed once daily during normal business hours while in use.

6.2 Cleaning is to be completed every six months, or as needed.

6.3 Calibration is to be performed annually by outside vendor (Alert Scientific Incorporated 1-800-872-2028) or whenever there is a noted temperature shift in the daily monitoring.

7.0 EQUIPMENT & SUPPLIES

7.1 Incubator

7.2 Calibrated thermometer

8.0 GENERAL INFORMATION

8.1 NA

9.0 PROCEDURE

9.1 Use/Monitoring

- 9.1.1 Assemble unit as outlined in the instruction manual.
- 9.1.2 Place unit in a clear, draft free environment.
- 9.1.3 Ensure that all ventilation holes in the incubator are not blocked.
- 9.1.4 Turn the "Power" switch to the ON position.
- 9.1.5 Use the temperature control knob to set the desired temperature. Calibration shall be performed as stated in section 9.2.

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9.1.6 When placing or removing items the door should not be open for extended periods of time. Items should be placed or removed and the door shut immediately.

9.1.7 A thermometer shall be positioned in the geometric center of the incubator.

9.1.8 Optimal temperature range for the pharmacy can change depending on the required incubation temperature. The temperature will be verified per the calibration procedure when the set point is changed.

9.1.9 Daily readings shall be recorded on the "Daily Incubator Monitoring Log". (Acceptable temperature range 30 to 35°C)

9.1.10 If the temperature of the incubator falls out of the optimal temperature range, items must be removed immediately and placed in an alternate incubator.

9.1.11 Items that are damaged by the variation in temperature shall be discarded.

9.1.12 At the end of each month, place the log in the quality assurance file.

9.2 Calibration

9.2.1 A digital thermometer of the proper range shall be positioned in the middle of one of the incubator shelves. Allow one hour for the thermometer to equilibrate with the environment.

9.2.2 At the end of the hour, read the thermometer. If the reading does not agree with the temperature desired, adjust the incubator temperature control accordingly.

9.2.3 Allow one hour for the incubator to adjust to the new setting and the thermometer to equilibrate with the environment.

9.2.4 At the end of the hour, read the thermometer. Repeat this process until the desired temperature is achieved.

9.2.5 Readings shall be recorded on the "Daily Incubator Monitoring log".

9.2.6 At the end of each month, place the log in the quality assurance file.

9.3 Cleaning

9.3.1 Remove any materials that may be harmed by the cleaning solution or the temperature change that will occur when the door is open for cleaning.

9.3.2 The interior bottom, sides and shelves of the unit can be cleaned using 70% IPA.

9.3.3 Allow to dry thoroughly before re-starting unit.

9.3.4 The exterior can be cleaned using 70% IPA.

9.3.5 *Calibration* - Outside Vendor (Alert Scientific Incorporated-1-800-872-2028). According to vendor specifications.

9.4 Maintenance

9.4.1 Check circulating fans for excessive noise and build up of lint on the blades.

9.4.2 Wipe off door gasket and inspect for cracks or defects.

9.4.3 Lubricate door hinges as needed.

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10.0 ATTACHMENTS

10.1 Attachment 1 - Daily Incubator Monitoring Log

HISTORY

Version Number	Date Effective	Description of Change	Change Request Number
1.0	03/28/06	New SOP	CR06021
2.0	NA	Took out drug products from 9.1.10	CR07011
3.0	08/08/08	Changed Attachment 1/ Minor Changes/Took out Attachment 2	CR08015

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TITLE: USE, VERIFICATION AND MAINTENANCE OF THE INCUBATOR

SOP NUMBER: 4.070 VERSION NUMBER: 3.0

DAILY INCUBATOR MONITORING LOG

Month/Year: ______________________ Incubator ID: __________ Incubator Location: ______________________

Date	Time	Temperature (°C)	Initials	Date	Time	Temperature (°C)	Initials
/01/				/17/			
/02/				/18/			
/03/				/19/			
/04/				/20/			
/05/				/21/			
/06/				/22/			
/07/				/23/			
/08/				/24/			
/09/				/25/			
/10/				/26/			
/11/				/27/			
/12/				/28/			
/13/				/29/			
/14/				/30/			
/15/				/31/			
/16/							

(Acceptable Range 30°C to 35°C)

Quality Control: ______________________ Date: ______________

Reviewed By: ______________________ Date: ______________

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TITLE: USE AND MAINTENANCE OF THE EXAKT THREE ROLL OINTMENT MILL	
SOP NUMBER: 4.090	**VERSION NUMBER: 2.0**
Non-Sterile Laboratory	Effective Date 08-15-07
Originator:	
Reviewer:	

1.0 PURPOSE

1.1. The purpose of this procedure is to outline the use and maintenance of the Exakt Three Roll Ointment Mill.

2.0 SCOPE

2.1. This procedure applies to all personnel using the Exakt Three Roll Ointment Mill at New England Compounding Center.

3.0 RESPONSIBILITY

3.1. The Pharmacist-in-charge or other qualified personnel shall supervise this procedure or document that another staff member has been designated to complete the task.

4.0 REFERENCES

4.1. Instruction manual

5.0 DEFINITIONS

5.1. N/A

6.0 FREQUENCY

6.1. Maintenance shall be performed as required per instruction manual.

7.0 EQUIPMENT & SUPPLIES

7.1. Exakt Three Roll Ointment Mill

8.0 GENERAL INFORMATION

8.1. N/A

9.0 PROCEDURE

9.1. Use

- 9.1.1. Ensure that the unit is installed on a firmly supported bench top.
- 9.1.2. Check the roller surfaces, guides, and scrapers for cleanliness prior to use.
- 9.1.3. Prepare the product to be processed and keep a spatula ready for feeding the product into the hopper.
- 9.1.4. Install the plastic guides and the hopper, if necessary, and attach the scraper system.
- 9.1.5. Adjust the smallest possible roller gap, then drop product into the hopper using a spatula. Switch the unit on and continue applying the product using a spatula.
- 9.1.6. Use a separate spatula for taking product off the scraper to ensure that the finely ground product is not contaminated with yet-to-be-milled product.
- 9.1.7. The throughput can be increased by gradually increasing the rear roller gap. If the product spreads out laterally over the front roller, decrease the rear roller gap until the product flow on the front rollers is the same width as the plastic guides.

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9.1.8. Clean the machine immediately after use.

9.2. Cleaning and Maintenance

9.2.1. After each use and whenever the product is changed:

9.2.1.1. Check the guides for dirt and signs of wear and clean/replace them if necessary.

9.2.1.2. Check and clean the rollers.

9.2.1.2.1. Remove the guides and the scraper.

9.2.1.2.2. Clean the rollers using paper towels and 70% IPA.

9.2.1.2.3. When necessary, clean rollers with soft scrub followed by distilled water then 70% IPA.

9.2.1.2.4. Do not spray the unit with or immerse it in water, solvent or other liquid.

9.2.1.2.5. Check the scraper knife for dirt and signs of wear and clean/replace if necessary.

9.2.1.2.6. If the product is not removed uniformly by the scraper system, check and adjust the contact pressure.

10.0 ATTACHMENTS

10.1. N/A

11.0 HISTORY

Version Number	Date Effective	Description of Change	Change Request Number
1.0	03/08/06	New SOP	CR06050
2.0	08/15/07	Annual Review and Text Changes	CR07003

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TITLE: USE, CALIBRATION AND MAINTENANCE OF THE BAXA REPEATER PUMP	
SOP NUMBER: 4.100	**VERSION NUMBER: 1.0**
Non-Sterile and Sterile Laboratory	Effective Date 03-28-06
Originator:	
Reviewer:	

1.0 PURPOSE

1.1 The purpose of this procedure is to outline the use and maintenance of the Baxa Repeater Pump.

2.0 SCOPE

2.1 This procedure applies to all personnel using the Baxa Repeater Pump at New England Compounding Center.

3.0 RESPONSIBILITY

3.1 The Pharmacist-in-charge shall supervise this procedure or document that another staff member has been designated to complete the task.

4.0 REFERENCES

4.1 Instruction manual

5.0 DEFINITIONS

5.1 N/A

6.0 FREQUENCY

6.1 Calibration must be performed prior to procedures that are volume sensitive.

6.2 The unit should be cleaned after each use.

7.0 EQUIPMENT & SUPPLIES

7.1 Baxa Repeater Pump

7.2 70% isopropyl alcohol

7.3 Low-lint wipes

7.4 Mild detergent solution

7.5 Luer lock syringes

8.0 GENERAL INFORMATION

8.1 Do not submerge the unit in water or cleaning solution.

8.2 Do not remove the exterior cover of the unit.

9.0 PROCEDURE

9.1 Use

9.1.1 If the product has been previously sterilized (autoclaved, filtered, etc.), a sterile tube set must be used. If the procedure is part of the sterilization process (filtration), a non-sterile tube set may be utilized.

9.1.2 Open the top lid. The front of the pump should be facing the user.

9.1.3 Grasp the blue connector on the inlet side (spike, bag or weight) and install into the channel between the back of the pump and the rotor section.

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9.1.4 Manually rotate the pump head to align with one of the rotor slots.

9.1.5 Insert tubing into the slot and rotate the pump head counterclockwise to "walk" the silicone tubing section around the rotor.

9.1.6 Place the blue connector in the channel on the right side of the pump.

9.1.7 Move the rotor back and forth several times to make sure that it moves freely.

9.1.8 Prime the tubing to remove air.

9.1.9 Close the top lid and clear the pump memory.

  9.1.9.1 Press **(function)** and **C/CE** at the same time.

  9.1.9.2 Press **Clear Units Filled.**

9.1.10 Select the volume to be dispensed.

  9.1.10.1 Press **Volume.**

  9.1.10.2 Select the volume to be dispensed.

9.1.11 Press **Start/Stop** to dispense the programmed volume.

9.2 Calibration

9.2.1 Enter the desired volume to be dispensed (including any overfill).

9.2.2 Attach the appropriate syringe to the filling end of the tube set.

9.2.3 Press **Start/Stop.**

9.2.4 If the volume reading is not accurate, adjust as follows.

  9.2.4.1 Press the **Adjust** pad.

  9.2.4.2 Enter the actual volume dispensed.

  9.2.4.3 Press the **Adjust** pad again.

  9.2.4.4 Press **Start/Stop** to dispense another sample.

  9.2.4.5 If the reading is still not accurate, repeat steps 9.2.4.1 through 9.2.4.4.

9.2.5 If the display reads **Readjust**, repeat the above steps to recalibrate the unit.

9.2.6 Do not change any settings such as speed, needle size, filter size or flow direction (forward/backward) once calibration is complete. The unit must be recalibrated if these settings are changed.

9.2.7 Do not turn the unit off after it has been calibrated. The unit must be recalibrated if turned off.

9.3 Cleaning and Maintenance

9.3.1 Pump Cleaning

  9.3.1.1 Unplug the unit.

  9.3.1.2 Use a low-lint wipe and sterile 70% isopropyl alcohol to clean the exterior sides, top, back and bottom.

  9.3.1.3 Use a mild detergent solution or warm water to clean the faceplate.

9.3.2 Rotor Assembly Cleaning

  9.3.2.1 All spills in the housing should be carefully cleaned immediately. Moisture-either from the spilled liquid or detergent-that migrates into the circuitry will damage the electronics.

03-28-06

9.3.2.2 Dried dextrose and saline solutions may cause the rotor to "freeze". If this occurs, first try to loosen the rollers (on the rotor) by turning them with your hand (DO NOT USE PLIERS). If this doesn't work, remove the rotor as follows.

9.3.2.3 Remove the rotor by loosening the setscrews with a 2.5mm alan wrench.

9.3.2.4 Pull on the top of the rotor assembly to remove it.

9.3.2.5 If the rotor is stuck, remove the cap on top of the rotor. Insert a 5mm bolt into the threaded hole and turn clock wise to pull off the rotor.

9.3.2.6 Soak the rotor in hot water and wash with a mild detergent solution.

9.3.2.7 Dry the rotor using a low-lint wipe.

9.3.2.8 Replace the rotor assembly.

9.3.3 The pump should be stored on the appropriate stand.

9.3.4 Pump(s) used in the clean room shall remain in the clean room and shall not be used for non-sterile applications unless decontaminated prior to reintroduction to the clean room.

10.0 ATTACHMENTS

10.1 N/A

11.0 HISTORY

Version Number	Date Effective	Description of Change	Change Request Number
1.0	03-28-06	New SOP	CR06051

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RMW
03-28-06

TITLE: USE AND MAINTENANCE OF THE CAPSULE MACHINE

SOP NUMBER: 4.110 **VERSION NUMBER: 2.0**

Non-Sterile Laboratory Effective Date 09-18-07

Originator:

Reviewer: Barry J Cadden

1.0 PURPOSE

1.1 The purpose of this procedure is to outline the use and maintenance of the capsule machine.

2.0 SCOPE

2.1 This procedure applies to all personnel using the capsule machine at New England Compounding Center.

3.0 RESPONSIBILITY

3.1 The Pharmacist-in-charge or other qualified personal shall supervise this procedure or document that another staff member has been designated to complete the task.

4.0 REFERENCES

4.1 Instruction manual/ DVD

5.0 DEFINITIONS

5.1 N/A

6.0 FREQUENCY

6.1 Maintenance shall be performed as required per instruction manual.

7.0 EQUIPMENT & SUPPLIES

7.1 Capsule machine

7.2 Powder scraper

7.3 Mild soap solution

7.4 Sponge

8.0 GENERAL INFORMATION

8.1 Store all components only when clean and dry.

8.2 Store plates flat and do not place heavy items on top of the components.

8.3 Do not clean any component in the dishwasher.

8.4 Do not use a hair dryer or heat gun to dry components.

8.5 Refer to instruction manual for troubleshooting.

9.0 PROCEDURE

9.1 Use

9.1.1 Identification Notches for Separator, Pinch and Loader Plates

9.1.1.1 Choose the separator, pinch and loader plates that correspond to the size capsule that will be used. Three plates are required for the base unit, and two plates are required for the loader.

9.1.1.2 Open the front door and insert the pinch plates (black on bottom, white on top) with the notches facing the front door.

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9.1.1.3 Close the front door and use the pinch knobs to hold the door in place, but **do not tighten the pinch knobs**.

9.1.1.4 Install the corresponding separator plate without the retainer plate, with notches facing front door.

9.1.2 The Loader

9.1.2.1 Choose the plates that correspond to the size capsule that will be used.

9.1.2.2 Pull out and slide down the plate retainer block.

9.1.2.3 Install the white plate on top, black plate on the bottom, with the notches facing toward the retainer block.

9.1.2.4 Slide the retainer block up until it locks in place, and make sure that the white plate can be depressed into the spring block smoothly.

9.1.3 Adjustments

9.1.3.1 With the pinch plates in place and the separator plate assembly removed, take four capsules and manually separate them.

9.1.3.2 Place the bottoms in the four corner holes of the pinch plates and turn the depth adjustment screws clockwise/counterclockwise to raise/lower the depth plate.

9.1.3.3 Adjust the height of the depth plate so that the tops are flush with (or slightly lower than) the top pinch plate.

9.1.3.4 Adjustments may be made while the machine is full, but this method is not recommended.

9.1.4 Loading Capsules

9.1.4.1 Place the appropriate capsules on top of the loader plates, and using a rocking motion, fill all the top slots with the capsules (50 slots for the #100 count capsule machine or 150 for the #300 count capsule machine).

9.1.4.2 Pour excess capsules into another receptacle.

9.1.4.3 Place the loader on the capsule machine separator plate with the retainer plate removed.

9.1.4.4 The loader should slide freely left to right on the rails when positioned correctly.

9.1.4.5 Slide the unit all the way to the left or to the right, and **remember where the first 50 capsules were dropped**.

9.1.4.6 Gently push the white plate into the spring block.

9.1.4.7 Tap on the upper plate to release any capsules that may be stuck.

9.1.4.8 Shake the separator plate to set the caps down before loading the next 50 capsules.

9.1.4.9 Repeat above steps to load the remaining 50 capsules (or 150 capsules for the 300 count machine), and slide the loader in the **opposite** direction used the first time.

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9.1.4.10 Make sure that all 100 capsules (or 300 capsules) are properly loaded. If not, correct the capsules manually.

9.1.4.11 Place the retainer back on top of the separator plate and turn the locking hubs on the aluminum rails inward to hold the retainer plate in place.

9.1.4.12 Close the front door.

9.1.5 Separating Capsules

9.1.5.1 Hand-tighten the pinch knobs as tight as possible.

9.1.5.2 Place thumbs on front blue post protruding above the separator plate.

9.1.5.3 Place fingers underneath the separator plate, gently pull up, then move to the rear and repeat.

9.1.5.4 Place the separator plate out of the way.

9.1.5.5 Loosen the pinch knobs and using a clean powder scraper, push the capsule bottoms down until they rest on the depth plate.

9.1.5.6 Make final adjustments to the depth adjustment screws, so that no capsules are seated above the pinch plates.

9.1.6 Filling Capsules

9.1.6.1 Place prepared capsule unit on vibrator plate.

9.1.6.2 Place powder dam and clips on top of the pinch plates.

9.1.6.3 Place the prepared powder in the center of the machine and dispense evenly over all capsules using the powder scraper.

9.1.6.4 Gradually increase vibrator setting and spread powders, using the powder scraper.

9.1.6.5 When capsules are filled to top and powder still remains, turn vibrator to the lowest setting and scrap powders to one side.

9.1.6.6 Tamp all the capsules with tamper and redistribute the powder over the capsules as needed. Do not tamp capsules with loose powder on top.

9.1.6.7 Repeat steps 9.1.6.3 through 9.1.6.4 until all powder is used.

9.1.6.8 Remove powder dam and clips.

9.1.7 Reassembling Capsules

9.1.7.1 Install the separator plate back onto the base, and make sure the thumbscrews are loose.

9.1.7.2 Place thumbs on top of the separator plate and forefingers under the depth plate.

9.1.7.3 Slowly and gently lift the depth plate. If the capsules do not reassemble immediately, the plates can be shifted left to right, and front to rear to align the bottoms and tops. Drop the depth plate to see if any capsules are resting on the depth plate. **Do not force the capsules back together.**

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9.1.7.4 Gently lift the separator plate, invert and use thumbs to lock each capsule one at a time.

9.1.7.5 Pour capsules on to a paper towel. Gather the four corners to make a "pouch".

9.1.7.6 Rub excess powder off of capsules by gently massaging the "pouch".

9.1.7.7 Pour the capsules into the appropriate capsule vial.

9.2 Cleaning and Maintenance

9.2.1 Clean with a mild soap solution and hot water using a sponge.

***NOTE:* Do not put any component of the capsule machine in the dishwasher.**

9.2.2 Tap water out of the holes and allow all components to drip dry.

9.2.3 Remove the pinch knobs and depth screws and clean the threads as needed.

10.0 ATTACHMENTS

10.1 N/A

11.0 HISTORY

Version Number	Date Effective	Description of Change	Change Request Number
1.0	03/28/06	New SOP	CR06052
2.0	09/18/07	Changes and Updates	CR07005

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04-18-07

TITLE: USE AND MAINTENANCE OF ANPROLENE GAS STERILIZER	
SOP NUMBER: 4.111	**VERSION NUMBER: 2.0**
Sterile Laboratory	Effective Date 06/10/11
Originator:	
Reviewer:	

1.0 PURPOSE

1.1 The purpose of this procedure is to define the use and maintenance of the Anprolene gas sterilizer.

2.0 SCOPE

2.1 This procedure applies to all personnel who use the Anprolene gas sterilizer.

3.0 RESPONSIBILITY

3.1 Personnel using the Anprolene gas sterilizer are responsible for complying with this procedure and ensuring that they are trained appropriately.

3.2 The Pharmacist in charge shall manage this procedure and ensure that personnel comply with this procedure.

4.0 REFERENCES

4.1 Anprolene Gas Sterilizer “Study Guide”

4.2 Anprolene Gas Sterilizer “Owner’s Manual”

5.0 DEFINITIONS

N/A

6.0 FREQUENCY

N/A

7.0 EQUIPMENT & SUPPLIES

7.1 Dosimeter®

7.2 Humidichip® and Humiditube®

7.3 Bio-Indicator

7.4 Sterilization Liner Bag

7.5 Ethylene Oxide Gas Tube

8.0 ATTACHMENTS

8.1 Attachment 1 - Steritest Log

8.2 Attachment 2 - Sterilization Record

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9.0 GENERAL INFORMATION

9.1 Review Material Safety Data Sheet for Ethylene Oxide when working with gas sterilizer.

9.2 Ethylene Oxide sterilization is temperature and humidity dependant. For the most effective sterilization, the temperature throughout the sterilization process should between 68°F-91 °F and the humidity above 35%.

9.3 Do not use Ethylene Oxide sterilization for liquids, food, or drugs.

9.4 Do not re-use sterilization liner bags.

9.5 Do not interrupt a sterilization cycle.

9.6 If contact with ethylene oxide liquid occurs, immediately wash hands for at least 15 minutes and contact supervisor.

9.7 The 16 hour cycle ends with a 1, 3, or 4 hour or 5 minute quick purge cycle which flushes with fresh air.

10.0 PROCEDURE

10.1 Steritest Qualification

10.1.1 Document receipt of the Steritest on Attachment 1. Complete all applicable sections.

10.1.2 Test 1 (one) Steritest from the lot received to ensure the biological indicator (BI) is positive.

10.1.2.1 Break ampule in Steritest pouch and ensure that liquid covers white strip.

10.1.2.2 Incubate at 35 - 40°C for 2 days.

10.1.2.3 Read results. Clear red liquid indicates BI is successful. Cloudy yellowish liquid indicates BI is unsuccessful.

10.1.2.4 Document results on Attachment 1.

10.1.2.5 Use the lot only if BI is successful. Do not use lot if BI is unsuccessful.

10.2 Material Preparation

10.2.1 For materials that have multiple parts such as syringes, disassemble the parts to ensure an unobstructed path for sterilization.

10.2.2 Clean items by washing with a detergent, if not already cleaned.

10.2.3 Dry items after washing.

10.2.4 Wrap the items in an appropriately sized sterilization pouch that is compatible with Ethylene Oxide sterilization.

10.3 Set Up Sterilization Cycle

10.3.1 Document the items that are being sterilized along with the lot numbers and expirations of the sterilizer materials on Attachment 2.

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10.3.2 Assign a sequential numerical cycle number, starting with 1, and document on Attachment 2 and on the outside of each sterilization pouch.

Note: The cycle number is recorded on the items that are being sterilized to provide traceability on the corresponding formulary worksheet where the sterilized items are used.

10.3.3 Place items to be sterilized in a new sterilization liner bag.

10.3.4 Insert Dosimeter and Bio-Indicator into the least accessible part of the bag.

10.3.5 Place a Humidichip into the Humidtube and place into sterilization liner bag.

10.3.6 Remove tape and tab from gas tube, insert into bag and place in the front of the bag.

10.3.7 Place the gas release bag on top of the items in the sterilization liner bag where it can be broken easily.

10.3.8 Remove any excess air and heat seal bag twice on the opening of the bag.

10.4 Starting Sterilization Cycle

10.4.1 Push load button.

10.4.2 Enter number of bags…press **ENTER** button.

10.4.3 Labels will print, (two per bag). Place one label on bag and one label on log sheet.

Note: *There is a 10 minute count down until the alarm will sound.*

10.4.4 Once all bags are in the gas sterilizer, press ***blue*** button on the gas tube and close door. (16 hour cycle begins).

10.5 Unloading the Sterilizer

10.5.1 PRESS UNLOAD BUTTON (5 minute purge cycle begins).

10.5.2 DOOR IS LOCKED (Printer will print out cycle log sheet, attach to the sterilization record sheet).

10.5.3 (DOOR WILL UNLOCK), Open door, SLICE bags at the top.

10.5.4 CLOSE DOOR – Press 5 (ENTER), 5 MINUTE PURGE (2nd purge cycle).

10.5.5 After the COUNTER times down, the 2nd cycle will begin, (DOOR WILL LOCK AGAIN).

10.5.6 Once cycle is over, door will unlock. Remove all bags from sterilizer and close door.

10.5.7 Remove the Humidichip, Gas tube, and Bio Indicator. (The humidichip can be thrown away with the gas tube. Incubate the bio indicator for 24hrs at 35 - 40°C.

10.5.8 Re-seal all the bags with the heat sealer.

10.5.9 Log all the test results on the sterilization record.

10.6 Place the sterilized items in quarantine until results of Steritest incubation are obtained.

10.6.1 Examine the Dosimeter. The indicator should have turned from yellow to blue and extend up to or past the triangle.

Note: The Dosimeter is an indicator of time, temperature, and gas concentration during the sterilization cycle. It does not give any indication of sterility. A sterilization cycle may still be successful.

10.6.2 Break ampule in Steritest pouch without opening the pouch and ensure that liquid covers white strip.

10.6.3 Incubate at 35 - 40°C for 2 days.

10.6.4 Read results.

10.6.5 If the culture medium is clear and the color remains blue-green, the spores were sterilized and the cycle was successful.

10.6.6 If the culture medium is cloudy and the color is yellow, the spores were not sterilized and the cycle was not successful.

10.6.7 Document results on Attachment 2.

10.6.8 If cycle was not successful. Regas. Following instructions from 10.3 through 10.5.

10.7 Maintenance

10.7.1 Clean the interior and exterior surfaces of the sterilizer when visibly dirty with a cotton cloth and mild detergent.

10.7.2 Document all maintenance and cleaning on "Log of Maintenance and Cleaning (L-MAC)". (SOP 1.040)

10.8 Preventative Maintenance (PM)

- Done annually by Anderson Products, Inc. 1-800-523-1276.

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11.0 HISTORY

Version Number	Description of Change	Change Request Number
1.0	New SOP	N/A
2.0	Changes to match new gas sterilizer	CR11002

06-10-11

ATTACHMENT 1 – STERITEST LOG

Steritest Lot #	Date Received	Quantity Received	Exp Date	Date Put on Test	Results (pos/neg)	Initial/Date

STERILIZATION RECORD

Cycle #/Date:	Time Started/Cycle Length:
Biological Lot#:	Exp Date:
Dosimeter Lot #	Exp Date:
Ethylene Oxide Lot #	Exp Date:
Humidichip Lot #	Exp Date:

Bag #	List of items being Sterilized	Quantity	Bio-Indicator Pass / Fail	Dosimeter Pass / Fail
1			P / F	P / F
2			P / F	P / F
3			P / F	P / F
4			P / F	P / F
5			P / F	P / F
6			P / F	P / F
7			P / F	P / F
8			P / F	P / F
9			P / F	P / F
10			P / F	P / F

Reviewed by: ______________________ Date: ____________

TITLE: OUT PATIENT MEDICATION RECORDS SYSTEM	
SOP NUMBER: 5.010	**VERSION NUMBER: 2.0**
Non-Sterile and Sterile laboratory	Effective Date 03/08/07
Originator:	
Reviewer:	

1.0 PURPOSE

1.1 This procedure will outline the requirements for recording patient medication records to ensure that all drugs and other therapies the patient is receiving do not create interactions with the compounded preparation.

2.0 SCOPE

2.1 This procedure applies to all compounding personnel at New England Compounding Center.

3.0 RESPONSIBILITY

3.1 The Pharmacist-in-charge shall supervise this procedure or document that another staff member has been designated to complete the task.

4.0 REFERENCES

4.1 N/A

5.0 DEFINITIONS

5.1 N/A

6.0 FREQUENCY

6.1 A Patient Medication Record shall be completed before a compound is prepared and dispensed to the patient.

7.0 EQUIPMENT & SUPPLIES

7.1 Original or refill prescription order for the compounded preparation

8.0 GENERAL INFORMATION

8.1 N/A

9.0 PROCEDURE

9.1 A certain amount of information shall be collected from the patient or caregiver to prevent complications during drug therapy. The following items, at a minimum, shall be obtained:

- 9.1.1 Date preparation dispensed
- 9.1.2 Patient's full name, address, telephone number and alternate phone number (if applicable)
- 9.1.3 Patient's date of birth and gender
- 9.1.4 Prescription number
- 9.1.5 Preparation name (active ingredients) and dosage form, compounded ingredients
- 9.1.6 Amount dispensed
- 9.1.7 Dispensing pharmacists initials

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9.1.8 Patient directions as counseled to the patient

9.1.9 All other drugs patient is receiving from all pharmacies (including all over-the-counter medications) and health conditions.

9.1.10 Known food/drug allergies or sensitivities

9.1.11 Primary diagnosis

9.2 The information above is entered into a computer program.

9.3 A drug utilization review (DUR) shall be completed before dispensing the compounded preparation to the patient.

9.4 The medication records form shall be updated as therapy changes or as patient situations dictate.

10.0 HISTORY

Version Number	Date Effective	Description of Change	Change Request Number
1.0	030806	New SOP	CR06023
2.0	020207	Annual Review	CR06069

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03-05-07

TITLE: OUTPATIENT PRESCRIPTION PROCESSING: COUNSELING, HIPPA AND COMPLAINTS	
SOP NUMBER: 5.020	**VERSION NUMBER: 5.0**
Non-Sterile and Sterile Laboratory	Effective Date 07/25/11
Originator:	
Reviewer:	

1.0 PURPOSE

1.1 This procedure is intended to ensure that the patient or care giver understands how to use the compounded preparation and will outline the requirements for patient surveys and/or grievances related to the compounded preparations received and/or the quality of care provided by New England Compounding Center.

2.0 SCOPE

2.1 This procedure applies to all personnel at New England Compounding Center.

3.0 RESPONSIBILITY

3.1 The Pharmacist-in-charge shall supervise this procedure or outpatient services employee or document that another staff member has been designated to complete the task.

4.0 REFERENCES

4.1 SOP 5.010 "Patient Medication Records System"

5.0 DEFINITIONS

5.1 N/A

6.0 FREQUENCY

6.1 This procedure must be followed when a customer complaint is issued or when an incident (error on a prescription, patient injury or side effects resulting from drug therapy, unsatisfactory care, split tube, etc.) has occurred.

6.2 Counseling is offered with every new prescription, or additionally upon request.

7.0 EQUIPMENT & SUPPLIES

7.1 Medication Records System (stored in computer)

7.2 Compounded preparation

7.3 Patient information material

8.0 GENERAL INFORMATION

8.1 N/A

9.0 PROCEDURE

9.1 Incident Reports

9.1.1 Personnel who receive complaints shall complete a "Customer Complaint Record" (Attachment 1).

9.1.2 All reports shall be completed and reviewed within 48 hours of receiving a customer complaint or observing non-compliance.

9.1.2.1 The report shall be completed and signed by the Pharmacist-in-charge or designee.

9.1.2.2 The patient, caregiver, or family members shall be contacted within 48 business hours, and the complaint shall be discussed entirely.

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9.1.3 The customer complaint is then assigned a number based on the type of complaint.

9.1.3.1 The results of the complaint shall be logged on the "Customer Complaint Log" (Attachment 2).

9.1.3.2 In the event that the patient responded to the compounded product adversely, that complaint is logged on the "Adverse Event Complaint Log" (Attachment 3).

9.1.3.3 The report will be assigned a number on the "Adverse Event Complaint Log" (Attachment 3) (see also SOP 5.030).

9.2 Each completed complaint/incident report shall be retained in a quality assurance file.

10.0 Outpatient Counseling

10.1 Patients and/or caregivers with a new prescription for a compounded preparation shall be counseled on the appropriate use of the compounded preparation, any adverse effects the patient should be aware of and any additional information relevant to the compounded preparation.

10.2 Patients with refills for compounded preparations shall be counseled at the patient's request or upon noticing that the patient may be noncompliant with therapy.

10.3 Patient instructions and information shall be distributed with the preparation, if available.

10.4 Patients that are counseled or are offered counseling at the time of pickup should sign and date the Outpatient Privacy and Consultation Log (Attachment 4).

11.0 Outpatient Privacy/ HIPAA

11.1 Outpatient HIPAA

11.1.1 Patient is given a copy of HIPAA form (Attachment 5) upon pickup of first prescription (This form is located on the shared drive).

11.1.2 Patient is asked to sign outpatient privacy and consultation log (Attachment 4).

11.1.3 These are kept on file.

12.0 Initial Outpatient Delivery

12.1.1 Patient is sent a copy of HIPAA form. (Attachment 5)

12.1.2 This is noted electronically in patient's profile.

13.0 **ATTACHMENTS**

13.1 Attachment 1 – Customer Complaint Record

13.2 Attachment 2 – Customer Complaint Log

13.3 Attachment 3 – Adverse Event Complaint Log

13.4 Attachment 4 – Outpatient Privacy and Consultation Log

13.5 Attachment 5 – HIPPA

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14.0 HISTORY

Version Number	Date Effective	Description of Change	Change Request Number
1.0	03/08/06	New SOP	CR06024
2.0	02/02/07	Annual Review	CR06070
5.0	07/22/11	Merged SOP 5.020 & 5.040 Added Attachments 1-3 from SOP 5.030 and deleted Attachments 1-3	CR11009

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CUSTOMER COMPLAINT RECORD

Customer Complaint Number: ____________ Date Received: ____________

CUSTOMER INFORMATION

Facility Name: ____________ Contact Name:

Address: ____________

Telephone: ____________ Fax:

Email: ____________ Date of Occurrence:

ADVERSE EVENT:	☐ Yes ☐ No
Product information (product names, lot #s, expiration dates, results):	
Describe the exact nature of the problem:	
Explain any death/injury/illness that has occurred or may occur:	
Other complaints or additional information related to this complaint:	
Investigation required? If no, explain: (INVESTIGATION REQUIRED FOR ALL ADVERSE EVENTS)	
Root cause analysis (most probable cause of incident):	
Outcome of investigation (attach all applicable documentation):	
Return: ☐ No ☐ Yes	Tracking #

Completed By: ____________ Date: ____________

Processed By: ____________ Date: ____________

Reviewed By: ____________ Date: ____________

New England Compounding Center

SOP 5.020

Version 5.0

Attachment 1

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CUSTOMER COMPLAINT LOG

Date	Customer Complaint Number	Adverse Event	Brief Description of Complaint	Investigation Required	Outcome of Complaint	Return	Date of Completion	Monthly Review (Initials/Date)
	CC______ Facility Name:	☐ Yes ☐ No		☐ Yes ☐ No		☐ Yes ☐ No		
	CC______ Facility Name:	☐ Yes ☐ No		☐ Yes ☐ No		☐ Yes ☐ No		
	CC______ Facility Name:	☐ Yes ☐ No		☐ Yes ☐ No		☐ Yes ☐ No		
	CC______ Facility Name:	☐ Yes ☐ No		☐ Yes ☐ No		☐ Yes ☐ No		
	CC______ Facility Name:	☐ Yes ☐ No		☐ Yes ☐ No		☐ Yes ☐ No		

ADVERSE EVENT COMPLAINT LOG

Date	AE Complaint Number	Brief Description of Complaint	Investigation Required	Date of Customer Letter	Return	Outcome of Complaint	Date of Completion	Pharmacist-In-Charge Initials/Date
	AE________ Facility Name:		☐ Yes ☐ No		☐ Yes ☐ No			
	AE________ Facility Name:		☐ Yes ☐ No		☐ Yes ☐ No			
	AE________ Facility Name:		☐ Yes ☐ No		☐ Yes ☐ No			
	AE________ Facility Name:		☐ Yes ☐ No		☐ Yes ☐ No			
	AE________ Facility Name:		☐ Yes ☐ No		☐ Yes ☐ No			

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Attachment 5

Your Health Information Rights

Obtain a paper copy of the Notice upon request. You may request a copy of our current Notice at any time. Even if you have agreed to receive the Notice electronically, you are still entitled to a paper copy. You may obtain a paper copy from a pharmacy, mail service location or the Privacy Office.

Request a restriction on certain uses and disclosures of PHI. You have the right to request additional restrictions on our use or disclosure of your PHI by sending a written request to the Privacy Office. We are not required to agree to those restrictions. We cannot agree to restrictions on uses or disclosures that are legally required, or which are necessary to administer our business.

Inspect and obtain a copy of PHI. In most cases, you have the right to access and copy the PHI that we maintain about you. To inspect or copy your PHI, you must send a written request to the Privacy Office. We may charge you a fee for the costs of copying, mailing and supplies that are necessary to fulfill your request. We may deny your request to inspect and copy in certain limited circumstances.

Request an amendment of PHI. If you feel that PHI we maintain about you is incomplete or incorrect, you may request that we amend it. To request an amendment, you must send a written request to the Privacy Office. You must include a reason that supports your request. In certain cases, we may deny your request for amendment.

Receive an accounting of disclosures of PHI. You have the right to receive an accounting of the disclosures we have made of your PHI after April 14, 2003 for most purposes other than treatment, payment, or health care operations. The right to receive an accounting is subject to certain exceptions, restrictions, and limitations. To request an accounting, you must submit a request in writing to the Privacy Office. Your request must specify the time period. The time period may not be longer than six years and may not include dates before April 14, 2003.

Request communications of PHI by alternative means or at alternative locations. For instance, you may request that we contact you at a different residence or post office box. To request confidential communication of your PHI, you must submit a request in writing to the Privacy Office. Your request must tell us how or where you would like to be contacted. We will accommodate all reasonable requests.

Where to obtain forms for submitting written requests. You may obtain forms for submitting written requests from our Privacy Office at our Framingham, Massachusetts Pharmacy, or by contacting the Privacy Officer at New England Compounding Center, Privacy Office, 697 Waverly Street, Framingham, MA 01702 or toll-free by telephone at (800) 994-6322.

Incidental Disclosures

NECC will make reasonable efforts to avoid incidental disclosures of protected health information. An example of an incidental disclosure is conversations that may be overheard between the pharmacy staff and the patient at our pickup counter. To reduce the likelihood of this happening, our pharmacists will provide consultations with you at our pickup counter only when no other personnel are present.

Minors

If you are a minor who has lawfully provided consent for treatment and you wish for NECC to treat you as an adult for purposes of access to and disclosure of records related to such treatment, please notify a pharmacist or the Privacy Office.

For More Information or To Report a Problem

If you have questions or would like additional information about NECC's privacy practices, you may contact our Privacy Officer at our Framingham, Massachusetts Pharmacy, or via mail at New England Compounding Center, Privacy Office, 697 Waverly Street, Framingham, MA 01702 or toll-free by telephone at (800) 994-6322. If you believe your privacy rights have been violated, you can file a complaint with the Privacy Officer or with the Secretary of Health and Human Services. There will be no retaliation for filing a complaint.

Effective Date

This Notice is effective as of April 13, 2003.

Notice of Privacy Practices

New England Compounding Center

(NECC)

THIS NOTICE DESCRIBES THE PRIVACY PRACTICES OF NEW ENGLAND COMPOUNDING CENTER ("NECC"), HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

Notice of Privacy Practices

NECC is required by law to maintain the privacy of Protected Health Information ("PHI") and to provide you with notice of our legal duties and privacy practices with respect to PHI. PHI is information that may identify you and that relates to your past, present or future physical or mental health or condition and related health care services. This Notice of Privacy Practices ("Notice") describes how we may use and disclose PHI to carry out treatment, payment or health care operations and for other specified purposes that are permitted or required by law. The Notice also describes your rights with respect to your PHI. We are required to provide this notice to you by the Health Insurance Portability and Accountability Act ("HIPAA").

NECC is required to follow the terms of this Notice. We will not use or disclose your PHI without your written authorization, except as described or otherwise permitted by this Notice. We reserve the right to change our practices and this Notice and to make the new Notice effective for all PHI we maintain. Upon request, we will provide any revised Notice to you.

Examples of How We Use and Disclose Protected Health Information About You

The following categories describe different ways that we use and disclose your protected health information. We have provided you with examples in certain categories; however, not every use or disclosure in a category will be listed.

Treatment. We may use your health information to provide and coordinate the treatment, medications and services you receive. For example, we may contact you regarding compliance programs such as drug recommendations, therapeutic substitution, refill reminders, other product recommendations, counseling and drug utilization review (DUR), product recalls or disease state management.

Payment. We may use your health information for various payment-related functions. Example: We may contact your insurer, pharmacy benefit manager or other health care payor to determine whether it will pay for your medication and the amount of your co-payment. We will bill you or a third-party payor for the cost of medications dispensed to you. The information on or accompanying the bill may include information that identifies you, as well as the medications you are taking.

Health Care Operations. We may use your health information for certain operational, administrative and quality assurance activities. Example: We may use information in your health record to monitor the performance of the pharmacists providing treatment to you. This information will be used in an effort to continually improve the quality and effectiveness of the health care and service we provide. We may disclose health information to business associates if they need to receive this information to provide a service to us and will agree to abide by specific HIPAA rules relating to the protection of health information.

We may also use your health information to provide you with information about benefits available to you, and, in limited situations, about health-related products or services that may be of interest to you.

We are permitted to use or disclose your PHI for the following purposes. However, NECC may never have reason to make some of these disclosures.

To Communicate with Individuals Involved in Your Care or Payment for Your Care. We may disclose to a family member, other relative, close personal friend or any other person you identify, PHI directly relevant to that person's involvement in your care or payment related to your care.

Food and Drug Administration (FDA) and Massachusetts Board of Pharmacy (MBOP). We may disclose to the FDA or MBOP, or persons under the jurisdiction of the FDA or MBOP, PHI relative to adverse events with respect to drugs, foods, supplements, products and product defects, or post-marketing surveillance information to enable product recalls, repairs, or replacement.

Worker's Compensation. We may disclose your PHI to the extent authorized by and to the extent necessary to comply with laws relating to worker's compensation or other similar programs established by law.

Public Health. As required by law, we may disclose your PHI to public health or legal authorities charged with preventing or controlling disease, injury, or disability.

Law Enforcement. We may disclose your PHI for law enforcement purposes as required by law or in response to a subpoena or court order.

As Required by Law. We will disclose your PHI when required to do so by federal, state, or local law.

Health Oversight Activities. We may disclose your PHI to an oversight agency for activities authorized by law. These oversight activities include audits, investigations, inspections, and credentialing, as necessary for licensure and for the government to monitor the health care system, government programs, and compliance with civil rights laws.

Judicial and Administrative Proceedings. If you are involved in a lawsuit or a dispute, we may disclose your PHI in response to a court or administrative order. We may also disclose health information about you in response to a subpoena, discovery request, or other lawful process instituted by someone else involved in the dispute, but only if efforts have been made, either by the requesting party or us, to tell you about the request or to obtain an order protecting the information requested.

Research. We may disclose your PHI to researchers when their research has been approved by an institutional review board or privacy board that has reviewed the research proposal and established protocols to ensure the privacy of your information.

Coroners, Medical Examiners, and Funeral Directors. We may release your PHI to a coroner or medical examiner. This may be necessary, for example, to identify a deceased person or determine the cause of death. We may also disclose PHI to funeral directors consistent with applicable law to enable them to carry out their duties.

Organ or Tissue Procurement Organizations. Consistent with applicable law, we may disclose your PHI to organ procurement organizations or other entities engaged in the procurement, banking, or transplantation of organs for the purpose of tissue donation and transplant.

Notification. We may use or disclose your PHI to notify or assist in notifying a family member, personal representative, or another person responsible for your care, regarding your location and general condition.

Fundraising. We may contact you as part of a fundraising effort.

Correctional Institution. If you are or become an inmate of a correctional institution, we may disclose to the institution or its agents PHI necessary for your health and the health and safety of other individuals.

To Avert a Serious Threat to Health or Safety. We may use and disclose your PHI when necessary to prevent a serious threat to your health and safety or the health and safety of the public or another person.

Military and Veterans. If you are a member of the armed forces, we may release PHI about you as required by military command authorities. We may also release PHI about foreign military personnel to the appropriate foreign military authority.

National Security, Intelligence Activities, and Protective Services for the President and Others. We may release PHI about you to federal officials for intelligence, counterintelligence, protection to the President, and other national security activities authorized by law.

Victims of Abuse or Neglect. We may disclose PHI about you to a government authority if we reasonably believe you are a victim of abuse or neglect. We will only disclose this type of information to the extent required by law, if you agree to the disclosure, or if the disclosure is allowed by law and we believe it is necessary to prevent serious harm to you or someone else.

Other Uses and Disclosures of PHI. We will obtain your written authorization before using or disclosing your PHI for purposes other than those provided for above (or as otherwise permitted or required by law). You may revoke an authorization in writing at any time. Upon receipt of the written revocation, we will stop using or disclosing your PHI, except to the extent that we have already taken action in reliance on the authorization.

OUTPATIENT PRIVACY AND CONSULTATION LOG

Attachment 4

Date	Rx Number	Privacy	Consult	SIGNATURE

(12)

TITLE: CUSTOMER COMPLAINT HANDLING

SOP NUMBER: 5.030 **VERSION NUMBER: 3.0**

Non-Sterile and Sterile Laboratory Effective Date 03/08/07

Originator:

Reviewer:

1.0 PURPOSE

1.1 The purpose of this procedure is to establish a method for identifying, recording investigating and responding to facility related complaints.

2.0 SCOPE

2.1 This procedure applies to all personnel at New England Compounding Center.

3.0 RESPONSIBILITY

3.1 All personnel are responsible for recognizing and reporting customer complaints.

3.2 The Pharmacist-in-charge, or designee, shall be responsible for investigating and responding to complaints unless otherwise delegated.

3.3 The Pharmacist-in-charge, or designee, is responsible for maintaining complaint files.

4.0 REFERENCES

4.1 SOP 9.070 "Recall of Compounded Product"

5.0 DEFINITIONS

5.1 Complaint – Any notification (verbal, telephone, fax, mail, electronic communication) that a product or service is (1) in violation of any laws or regulations, (2) may have caused or contributed to illness, injury, or death, or (3) is alleged to have caused problems or a dissatisfaction not covered by the above.

5.2 Adverse Event (AE) – Any adverse patient event associated with the use of a drug in humans whether or not considered drug related including the following:

- 5.2.1 Death
- 5.2.2 Injury
- 5.2.3 Lack of therapeutic effect
- 5.2.4 Reactions or other adverse events
- 5.2.5 Overdose or other misuse
- 5.2.6 Incorrect product use
- 5.2.7 Drug withdrawal

6.0 EQUIPMENT & SUPPLIES

6.1 N/A

7.0 FREQUENCY

7.1 The complaint handling procedure shall be followed every time a complaint is received.

8.0 GENERAL INFORMATION

8.1 N/A

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9.0 PROCEDURE

9.1 Complaints may be filed by consumers, government agencies, trade associations, health care professionals or any other related source.

9.2 All complaints must be addressed to the Pharmacist-in-charge, or designee, immediately.

9.3 The Pharmacist-in-charge or designees shall assign a customer complaint number for each complaint received. The customer complaint number shall be "CCXXYYY," where XX is the last two digits of the current year and YYY is incremental beginning with 001 and ending at 999 for the entire year.

9.4 The Pharmacist-in-charge, or designee, should identify and document the specific facts involving the complaint. The Customer Complaint Record (Attachment 1) should include the following information from the individual filing the complaint:

9.4.1 Customer name and title

9.4.2 Date of occurrence and customer complaint number

9.4.3 Address, telephone number and fax number (if applicable)

9.4.4 E-mail address (if applicable)

9.4.5 Exact nature of the problem

9.4.6 Whether or not death, injury, or illness has occurred or may occur

9.4.7 Whether or not other individuals have complaints or additional information relating to the complaint and how to contact them

9.4.8 Any lot numbers, expiration dates, results, product name(s), etc. that may identify the exact product and issue in question

9.5 The Pharmacist-in-charge, or designee, shall evaluate each complaint and, if necessary, commission an investigation. If an investigation is not warranted, the reason for such conclusion must be documented on Attachment 1.

9.5.1 An investigation shall be initiated when the facts and circumstances surrounding a complaint are not immediately apparent. Investigations may include review of equipment status, material suitability, employee training, testing methodology, record keeping and any other actions that may have contributed to or could help resolve the issue.

9.5.2 Complaint investigations shall be initiated and resolved as quickly as possible.

9.5.3 Results of investigations shall be documented and retained with the Customer Complaint Record.

9.6 The Pharmacist-in-charge, or designee, must evaluate the potential for the occurrence of adverse health effects or inaccurate test data reporting. If there is a reasonable possibility that adverse health effects may occur or that inaccurate test data was released, the Pharmacist-in-charge shall immediately notify all affected customers and shall initiate a recall as per SOP 9.070, "Recall of Compounded Product."

9.7 Complaint files and all documents pertaining to the complaint shall be retained in a quality assurance file indefinitely.

9.8 Adverse Events

9.8.1 Receiving Adverse Events Complaints

9.8.1.1 Upon receipt of a complaint from a patient or customer, the person receiving the call must inquire if there was an adverse event associated

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with the complaint. Indicate on the complaint form by checking Yes or No.

9.8.1.2 Adverse event complaints are given priority over routine complaints and the investigation must be initiated within 24 hours of receiving the complaint.

9.8.2 Acknowledgment of Adverse Event Complaint

9.8.2.1 The customer should be notified that the adverse event complaint has been received and a formal investigation is underway. Results of the complaint should be provided to the customer upon closure of the complaint.

9.8.2.2 Request that the product be returned for further testing (if available).

9.8.3 Evaluation

9.8.3.1 A formal investigation should commence within 24 hours of receiving the complaint.

9.8.3.2 The investigation should include a review of all compounding documentation to determine if the product was compounded in accordance with the formulation worksheet.

9.8.3.3 Determine if any other adverse events have been reported associated with the product.

9.8.3.4 If the product was determined to be defective, the pharmacist-in-charge must determine if a recall is required. If the complaint could not be confirmed (no product defects) the pharmacist shall determine how to credit or replace the product.

9.8.4 Corrective and Preventative Actions

9.8.4.1 For defective product define what corrective actions were taken.

9.8.4.2 Define what steps will be taken to prevent a reoccurrence of the defect.

9.8.5 Review, Approval and Closure

9.8.5.1 The Compliance Control officer must review all adverse event complaints to determine if the appropriate corrective and preventative actions have been taken.

9.8.5.2 The pharmacist-in-charge must approve the closure of all adverse event complaints.

9.8.6 Adverse Event Files

9.8.6.1 The adverse event complaint number shall be "AEXXYYY," where XX is the last two digits of the current year and YYY is incremental beginning with 001 and ending at 999 for the entire year.

9.8.6.2 Adverse event complaints shall be maintained in a separate location from the complaint file or otherwise clearly identified as an adverse event.

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TITLE: CUSTOMER COMPLAINT HANDLING

SOP NUMBER: 5.030 **VERSION NUMBER: 3.0**

10.0 ATTACHMENTS

10.1 Attachment 1 – Customer Complaint Record

10.2 Attachment 2 – Customer Complaint Log

10.3 Attachment 3 – Adverse Event Complaint Log

11.0 HISTORY

Version Number	Date Effective	Description of Change	Change Request Number
1.0	03/08/06	New SOP	CR06025
2.0	04/13/06	Updated attachments.	CR06062
3.0	03/08/07	Annual update	CR06071

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CUSTOMER COMPLAINT RECORD

Customer Complaint Number: ________________ Date Received: ________________

CUSTOMER INFORMATION

Facility Name: ____________________

Contact Name:

Address: ____

Fax:

Telephone: ____________________

Date of Occurrence:

Email: ____________________

ADVERSE EVENT:	☐ Yes ☐ No
Product information (product names, lot #s, expiration dates, results):	
Describe the exact nature of the problem:	
Explain any death/injury/illness that has occurred or may occur:	
Other complaints or additional information related to this complaint:	
Investigation required? If no, explain: (INVESTIGATION REQUIRED FOR ALL ADVERSE EVENTS)	
Root cause analysis (most probable cause of incident):	
Outcome of investigation (attach all applicable documentation):	
Return: ☐ No ☐ Yes	Tracking #

Completed By: ______________________________ Date: ________________

Processed By: ______________________________ Date: ________________

Reviewed By: ______________________________ Date: ________________

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CUSTOMER COMPLAINT LOG

Date	Customer Complaint Number	Adverse Event	Brief Description of Complaint	Investigation Required	Outcome of Complaint	Return	Date of Completion	Monthly Review (Initials/Date)
	CC________ Facility Name:	☐ Yes ☐ No		☐ Yes ☐ No		☐ Yes ☐ No		
	CC________ Facility Name:	☐ Yes ☐ No		☐ Yes ☐ No		☐ Yes ☐ No		
	CC________ Facility Name:	☐ Yes ☐ No		☐ Yes ☐ No		☐ Yes ☐ No		
	CC________ Facility Name:	☐ Yes ☐ No		☐ Yes ☐ No		☐ Yes ☐ No		
	CC________ Facility Name:	☐ Yes ☐ No		☐ Yes ☐ No		☐ Yes ☐ No		

SOP 5.030

New England Compounding Center

Attachment 2

Version

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ADVERSE EVENT COMPLAINT LOG

Date	AE Complaint Number	Brief Description of Complaint	Investigation Required	Date of Customer Letter	Return	Outcome of Complaint	Date of Completion	Pharmacist-In-Charge Initials/Date
	AE________ Facility Name:		☐ Yes ☐ No		☐ Yes ☐ No			
	AE________ Facility Name:		☐ Yes ☐ No		☐ Yes ☐ No			
	AE________ Facility Name:		☐ Yes ☐ No		☐ Yes ☐ No			
	AE________ Facility Name:		☐ Yes ☐ No		☐ Yes ☐ No			
	AE________ Facility Name:		☐ Yes ☐ No		☐ Yes ☐ No			

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03-08-07

TITLE: DELIVERY OF COMPOUNDED PREPARATIONS
SOP NUMBER: 5.050 **VERSION NUMBER: 1.0**
Non-Sterile and Sterile Laboratory Effective Date: 3/08/06
Originator:
Reviewer:

1.0 PURPOSE

1.1 The purpose of this procedure is to ensure that compounded preparations are delivered to the patient or health care facility quickly and in a manner such that the product integrity, quality, safety and efficacy are not compromised.

2.0 SCOPE

2.1 This procedure applies to all delivery personnel at New England Compounding Center.

3.0 RESPONSIBILITY

3.1 The Pharmacist-in-charge shall supervise this procedure or document that another staff member has been designated to complete the task.

4.0 REFERENCES

4.1 USP Current Version <795> "Pharmaceutical Compounding – Non-Sterile Preparations"

4.2 USP Current Version <797> "Pharmaceutical Compounding – Sterile Preparations"

5.0 DEFINITIONS

5.1 N/A

6.0 FREQUENCY

6.1 This procedure shall be followed for each compounded preparation that is to be delivered.

7.0 EQUIPMENT & SUPPLIES

7.1 Compounded preparation(s) and appropriate equipment/devices if necessary

7.2 Appropriate delivery container

8.0 GENERAL INFORMATION

8.1 N/A

9.0 PROCEDURE

9.1 The responsible personnel shall assure that the compounded preparation is properly delivered to the patient or health care facility without compromising the product integrity, quality, safety and efficacy.

9.2 All compounded preparations shall be delivered in appropriate containers that will protect the preparation from wide variations in temperatures, structural damage or unapproved light sources. All compounded preparations must be delivered via a courier with traceability (i.e. FedEx, etc.).

9.3 All compounded preparations containing Class II medications require a signature upon delivery.

9.5 A material safety data sheet (MSDS) for each product used in the compounded preparation shall be available at the pharmacy in case a spill or accident occurs while delivering the product.

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9.6 Storage instructions shall be provided to the patient, caregiver, or healthcare facility to ensure that the product is stored appropriately.

9.7 Instructions shall be provided to the patient or caregiver on how to contact the pharmacist for patient counseling.

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11 ATTACHMENTS

10.1 N/A

11 HISTORY

Version Number	Date Effective	Description of Change	Change Request Number
1.0	03/08/06	New SOP	CR06027

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03-08-06

TITLE: CONTROLLED SUBSTANCES CIII to CV INVENTORY

SOP NUMBER: 5.070 **VERSION NUMBER: 3.0**

Non-Sterile and Sterile Laboratory Effective Date 07/15/11

Originator:

Reviewer:

1.0 PURPOSE

1.1 The purpose of this procedure is to establish requirements for receiving, tracking and destroying CIII to CV controlled substances.

2.0 SCOPE

2.1 This procedure applies to all compounding personnel at New England Compounding Center.

3.0 RESPONSIBILITY

3.1 The Pharmacist-in-charge shall supervise this procedure or document that another staff member has been designated to complete the task.

4.0 REFERENCES

4.1 N/A

5.0 DEFINITIONS

5.1 N/A

6.0 FREQUENCY

6.1 Quarterly

6.2 Upon receipt of new shipment of CIII to CV substances.

6.3 Every time a CIII to CV substance must be destroyed

7.0 EQUIPMENT & SUPPLIES

7.1 Appropriate state and federal laws governing controlled substances

7.2 Analytical or electronic balance

7.3 Controlled substance tracking binder

8.0 GENERAL INFORMATION

8.1 N/A

9.0 PROCEDURE

9.1 Upon receipt of a CIII to CV bulk powder, the material plus container shall be weighed to verify accuracy of weight from the supplier. (If a similar container is available, the container may be weighed and the scale may be tared before weighing the substance plus container).

9.1.1 The weight of the controlled substance plus container should be recorded on the CIII to CV Controlled Substance Record (Attachment 1).

9.2 The controlled substance used to compound preparations, the material plus container shall be weighed quarterly. This should be recorded on the appropriate space in the CIII to CV controlled substance record (Attachment 1).

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9.3 On the first business day of each quarter, "an inventory and use for specific chemical" report is run on the "Compounder" for each CIII to CV substance.

9.4 The weight of each drug utilized for the quarter is recorded in the appropriate space on the CIII to CV Record. (Attachment 1).

9.5 The difference between the actual and theoretical weight is calculated and recorded on Attachment 1).

9.6 Discrepancies greater that 10% must be investigated by the pharmacist in charge and a variance report completed (Attachment 2).

9.7 An informal inspection of controlled substances for upcoming expiration dates shall also be performed to avoid dispensing an expired product.

9.7.1 When expired controlled substances have been identified, they shall be taken out of inventory and prepared for destruction.

9.7.2 The expired controlled substances shall be documented on either the expired chemical log (Attachment 3) or the drug disposal log (Attachment 4) which shall include the following information:

9.7.2.1 Drug name
9.7.2.2 Manufacturer
9.7.2.3 Lot number
9.7.2.4 Expiration date
9.7.2.5 Number of vials (if applicable)
9.7.2.6 Reason for disposal (if applicable)
9.7.2.7 Approximate weight (if applicable)

9.7.3 Each completed Controlled Substance Record, Variance Report, and destruction logs shall be placed in a quality assurance file and shall be retained as required by the Massachusetts State Board of Pharmacy – Pharmacy Practice Rules and Regulations.

10.0 ATTACHMENTS

10.1 Attachment 1 – CIII to CV Controlled Substance Record
10.2 Attachment 2 – Controlled Substance Variance Report
10.3 Attachment 3 – Expired Chemical Log (CIII to CV)
10.4 Attachment 4 – Drug Disposal Log (CIII to CV)

11.0 HISTORY

Version Number	Date Effective	Description of Change	Change Request Number
1.0	03-08-06	New SOP	CR06029
2.0	03-08-07	Change from Controlled Substances to CIII to CV	CR06075
3.0	07/15/11	Changed monthly to quarterly, added Mass, and added manufacturer on attachments 1 & 2	CR11008

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CIII to CV CONTROLLED SUBSTANCE RECORD

Product: ______________________ **Lot#/Exp. Date:** ______________________

Date	Beginning Weight (Container & Chemical)	Amount of Drug Utilized during Month	Ending Weight (Container & Chemical)	Quantity Lost (%)	Performed By

Technician/Pharmacist: ______________________ Date: __________

Director of Pharmacy: ______________________ Date: __________

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CONTROLLED SUBSTANCE VARIANCE REPORT

Variance

A variance of **Plus / Minus** ____________________ of
(Circle one) (Enter quantity)

__________________________ was discovered on ______________.
(Name of Controlled Substance) (Date)

Signature: ________________________________ Date: ______________
(Pharmacist-In-Charge)

Resolution of Variance

Explanation: ____

____

____

____

____

____

____

____

Signature: ________________________________ Date: ______________
(Pharmacist-In-Charge)

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EXPIRED CHEMICAL LOG
(CIII to CV)

Drug Name	Manufacturer	Lot Number	Expiration Date	Approximate Weight

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DRUG DISPOSAL LOG
(CIII to CV)

Drug Name	Manufacturer	Lot Number	Expiration Date	Number of Vials	Reason for Disposal**

07-15-11

TITLE: CONTROLLED SUBSTANCES CII

SOP NUMBER: 5.080 **VERSION NUMBER: 1.0**

Sterile Laboratory Effective Date 03-19-08

Originator:

Reviewer:

1.0 PURPOSE

1.1 The purpose of this procedure is to establish requirements for receiving, tracking, destroying and accounting for loss or theft of Schedule 2 (CII) controlled substances.

2.0 SCOPE

2.1 This procedure applies to all New England Compounding Center employees authorized to handle controlled substances.

3.0 RESPONSIBILITY

3.1 The Pharmacist-in-charge shall supervise this procedure or document that another staff member has been designated to complete the task.

4.0 REFERENCES

4.1 Title 21, Chapter II, Federal Control Substance Act

4.2 247 CMR, Mass State Controlled Substance Regulations

4.3 MGL Chapter 94C

4.4 Federal Drug Control Act of 1970

4.5 Department of Public Health at 105 CMR 700

5.0 DEFINITIONS

5.1 Schedule II controlled substances are defined as having a high potential for abuse with severe psychological or physical dependence, but having legitimate medical value. A complete list of Schedule II controlled substances is provided by the DEA (See Attachment 1).

6.0 FREQUENCY

6.1 Ordering Schedule II (CII) controlled substances.

6.2 Receiving Schedule II (CII) controlled substances.

6.3 Each time a Schedule II (CII) controlled substance is used.

6.4 Within every 10 days.

6.5 Upon receipt of new shipment of CII substances.

6.6 Every time a CII substance must be destroyed.

6.7 When loss or theft of a controlled substance occurs.

7.0 EQUIPMENT & SUPPLIES

7.1 Controlled Substance Perpetual Inventory Log

7.2 Analytical or electronic balance

8.0 GENERAL INFORMATION

8.1 Handling of controlled substances must comply with all applicable local, state, and federal requirements.

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9.0 PROCEDURE

9.1 Placing Schedule II (CII) controlled substance orders

9.1.1 Director of pharmacy is responsible for placing all CII orders, by filling out and signing the DEA form 222.

9.1.2 Director of pharmacy will retain the blue "purchasers" copy and a FedEx copy. The remainder of the DEA form 222 will go to the appropriate CII vendor.

9.2 Receiving Schedule II (CII) controlled substance orders

9.2.1 Director of pharmacy is responsible for receiving all CII orders.

9.2.2 Director of pharmacy fills in the appropriate areas of DEA form 222 (date received, number of units received) for each product received.

9.2.3 Director of pharmacy will attach the appropriate documents to the "purchasers" DEA form 222 and will file.

9.3 Controlled Substances Storage and Access

9.3.1 Schedule II substances may only be handled by a pharmacist or a pharmacist's designee under direct supervision.

9.3.2 All schedule II substances must be stored separately from all other chemicals used in the pharmacy. The entire CII inventory shall be locked in a designated location and must be secured any time an authorized pharmacist is not supervising the storage area.

9.4 Controlled Substances Inventory Documentation and Verification

9.4.1 All schedule II substances must be signed into inventory upon receipt.

9.4.2 Before using any new container of schedule II substance, remove the safety seal immediately before use. Weigh the entire container and subtract the weight of its contents to determine container weight (CW). A determination of the quantity left in this container can subsequently be made by weighing the entire container and subtracting the weight of the container minus its contents (CW as previously determined).

9.4.3 Any schedule II substance used in a preparation must be signed out of inventory on the CII *Daily Use Log*. The amount of each chemical used is totaled at the end of each day and once within every 10 days all totals from CII Daily Use Log are transferred to the Master Binder. All totals are compared to the results of a physical inventory taken by an authorized pharmacist.

9.4.4 Amounts of all CII substances added to and taken from inventory shall be totaled and a theoretical inventory will be calculated.

9.4.5 Theoretical inventory is compared to actual inventory to ensure accuracy.

9.4.6 In the event of any discrepancy in inventory, an audit will be performed detailing the use of the CII in question. The audit is performed by first generating a report of all logs which used the CII in question. The report is then compared to the written record of the CII Daily Use Log.

9.4.7 If the discrepancy cannot be corrected by the audit, the pharmacist in charge shall complete a Controlled Substance Variance Report (see Attachment 2) and further investigation shall occur (see 9.4).

9.4.8 All documentation pertaining to controlled substances shall be stored and maintained in the pharmacy records for no less than 7 years.

9.5 Destruction of Schedule II Controlled Substances

9.5.1 The entire inventory of Schedule II substances will routinely be inspected for proximity to beyond use dates (BUD) in order to avoid dispensing an expired product.

9.5.2 Expired CII chemicals and preparations will be isolated for destruction along with all returned CII preparations and those made incorrectly. Expired chemicals and preparations shall be documented on the Expired Chemical Log (See Attachment 3) which shall include the following information.

9.3.2.1 Drug Name
9.3.2.2 Lot Number
9.3.2.3 Expiration Date
9.3.2.4 Number of units (Gm, mg, mL, vials)
9.3.2.5 Reason for disposal (if applicable)

9.5.3 Schedule II substances identified and documented for destruction will be removed from stock and placed in a separate location in the safe.

9.5.4 CII's set for destruction shall be returned using the contract Reverse Distributor licensed to handle CII drugs (Attachment 4).

9.5.5 All CII's set for destruction shall be logged on the Drug Disposal Log (CII) (Attachment 5), before being released to the Reverse Distributor (Attachment 4).

9.5.6 The pharmacist in charge shall complete DEA Form 41, Registrants Inventory of Drugs Surrendered (See Attachment 6), or an equivalent form provided by the Reverse Distributor and submit form to Reverse Distributor for approval.

9.5.7 The pharmacist shall receive a completed DEA Form 222 from the Reverse Distributor for CII drugs.

9.5.8 Complete forms shall be reviewed for accuracy prior to releasing the return drugs.

9.5.9 The pharmacist shall send expired medication via third party carrier to Reverse Distributor's facility.

9.5.10 All CII drugs returned shall be deducted from inventory in the Controlled Substance Perpetual Inventory Log.

9.5.11 The pharmacist shall document date sent on DEA Form 222 and send copy to DEA process center.

9.5.12 All documentation shall be stored for a minimum of 7 years.

9.6 Loss or Theft of Schedule II Controlled Substance

9.6.1 Employees authorized to handle controlled substances have the responsibility to report any shortage, loss, or theft of a controlled substance to the Pharmacist in Charge.

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9.6.2 If warranted, an investigation is conducted immediately and documented by the Manager of Record.

9.6.3 The Manager of Record shall report any theft or loss of controlled substances to the following three agencies immediately upon discovery:

9.6.3.1 The DEA Drug Diversion Unit shall be notified by using DEA FORM 106 (See Attachment 7).

9.6.3.2 The Department of Public Health, Drug Control Program shall be contacted by telephone (617-983-6700) and notified in writing within 7 days of the incident.

9.6.3.3 The Board of Registration in Pharmacy shall be sent a written report attached to the DEA Form 106 within 7 days.

10 ATTACHMENTS

10.1 Attachment 1 – US DEA, Office of Diversion Control; *Controlled Substances in Schedule II*

10.2 Attachment 2 – Controlled Substance Variance Report

10.3 Attachment 3 – Expired Chemical Log (CII)

10.4 Attachment 4 – Reverse Distributor Registrants Table

10.5 Attachment 5 – Drug Disposal Log (CII)

10.6 Attachment 6 – US DEA Form-41; Registrants Inventory of Drugs Surrendered

10.7 Attachment 7 – US DEA Form-106; Report of Theft or Loss of Controlled Substances

11 HISTORY

Version Number	Effective Date	Description of Change	Change Request Number
1.0	03-19-08	New SOP	CR08007

Attachment 1

U.S. DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
OFFICE OF DIVERSION CONTROL

HOME PRIVACY POLICY CONTACT US WHAT'S NEW HOT ITEMS SITEMAP SEARCH

Controlled Substance Schedules > List of Controlled Substances > **Schedule II**

Controlled Substances in Schedule II

This document is a general reference and not a comprehensive list. This list describes the basic or parent chemical and does not describe the salts, isomers and salts of isomers, esters, ethers and derivatives which may also be controlled substances.

DRUG_NAME	DEA NUMBER	CSA SCH	NARC	SYNONYM
1-Phenylcyclohexylamine	7460	II	N	PCP precursor
1-Piperidinocyclohexanecarbonitrile	8603	II	N	PCC, PCP precursor
Alfentanil	9737	II	Y	Alfenta
Alphaprodine	9010	II	Y	Nisentil
Amobarbital	2125	II	N	Amytal, Tuinal
Amphetamine	1100	II	N	Dexedrine, Adderall, Obetrol
Anileridine	9020	II	Y	Leritine
Benzoylecgonine	9180	II	Y	Cocaine metabolite
Bezitramide	9800	II	Y	Burgodin
Carfentanil	9743	II	Y	Wildnil
Coca Leaves	9040	II	Y	
Cocaine	9041	II	Y	Methyl benzoylecgonine, Crack
Codeine	9050	II	Y	Morphine methyl ester, methyl morphine
Dextropropoxyphene, bulk (non-dosage forms)	9273	II	Y	Propoxyphene
Dihydrocodeine	9120	II	Y	Didrate, Parzone
Dihydroetorphine	9334	II	Y	DHE
Diphenoxylate	9170	II	Y	
Diprenorphine	9058	II	Y	M50-50
Ecgonine	9180	II	Y	Cocaine precursor, in Coca leaves
Ethylmorphine	9190	II	Y	Dionin
Etorphine HCl	9059	II	Y	M 99
Fentanyl	9801	II	Y	Duragesic, Oralet, Actiq, Sublimaze, Innovar
Glutethimide	2550	II	N	Doriden, Dorimide
Hydrocodone	9193	II	Y	dihydrocodeinone
Hydromorphone	9150	II	Y	Dilaudid, dihydromorphinone
Isomethadone	9226	II	Y	Isoamidone
Levo-alphacetylmethadol	9648	II	Y	LAAM, long acting methadone, levomethadyl acetate
Levomethorphan	9210	II	Y	
Levorphanol	9220	II	Y	Levo-Dromoran
Meperidine	9230	II	Y	Demerol, Mepergan, pethidine
Meperidine intermediate-A	9232	II	Y	Meperidine precursor
Meperidine intermediate-B	9233	II	Y	Meperidine precursor, normeperidine
Meperidine intermediate-C	9234	II	Y	Meperidine precursor
Metazocine	9240	II	Y	
Methadone	9250	II	Y	Dolophine, Methadose, Amidone

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Methadone intermediate	9254	II	Y	Methadone precursor
Methamphetamine	1105	II	N	Desoxyn, D-desoxyephedrine, ICE, Crank, Speed
Methylphenidate	1724	II	N	Concerta, Ritalin, Methylin
Metopon	9260	II	Y	
Moramide-intermediate	9802	II	Y	
Morphine	9300	II	Y	MS Contin, Roxanol, Oramorph, RMS, MSIR
Nabilone	7379	II	N	Cesamet
Opium extracts	9610	II	Y	
Opium fluid extract	9620	II	Y	
Opium poppy	9650	II	Y	Papaver somniferum
Opium tincture	9630	II	Y	Laudanum
Opium, granulated	9640	II	Y	Granulated opium
Opium, powdered	9639	II	Y	Powdered opium
Opium, raw	9600	II	Y	Raw opium, gum opium
Oxycodone	9143	II	Y	OxyContin, Percocet, Endocet, Roxicodone, Roxicet,
Oxymorphone	9652	II	Y	Numorphan
Pentobarbital	2270	II	N	Nembutal
Phenazocine	9715	II	Y	Narphen, Prinadol
Phencyclidine	7471	II	N	PCP, Sernylan
Phenmetrazine	1631	II	N	Preludin
Phenylacetone	8501	II	N	P2P, phenyl-2-propanone, benzyl methyl ketone
Piminodine	9730	II	Y	
Poppy Straw	9650	II	Y	Opium poppy capsules, poppy heads
Poppy Straw Concentrate	9670	II	Y	Concentrate of Poppy Straw, CPS
Racemethorphan	9732	II	Y	
Racemorphan	9733	II	Y	Dromoran
Remifentanil	9739	II	Y	Ultiva
Secobarbital	2315	II	N	Seconal, Tuinal
Sufentanil	9740	II	Y	Sufenta
Thebaine	9333	II	Y	Precursor of many narcotics

Back to Top

Registration Support
Toll Free Number: 1-800-882-9539

ARCOS | Career Opportunities | Chemical Program | Controlled Substance Schedules | Drugs and Chemicals of Concern
Electronic Commerce Initiatives | | Federal Register Notices | Import Export | Links | Meetings and Events | NFLIS
Offices & Directories | On-Line Forms & Applications | Program Description | Publications | Questions & Answers | Quotas
Reports Required by 21 CFR | Title 21 Regulations & Codified CSA
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Attachment 2

CONTROLLED SUBSTANCE VARIANCE REPORT

Variance

A variance of **Plus / Minus** ______________________ of
(Circle one) (Enter quantity)

____________________________ was discovered on ______________.
(Name of Controlled Substance) (Date)

Signature: ________________________________ Date: ______________
(Pharmacist-In-Charge)

Resolution of Variance

Explanation: ____

____

____

____

____

____

____

____

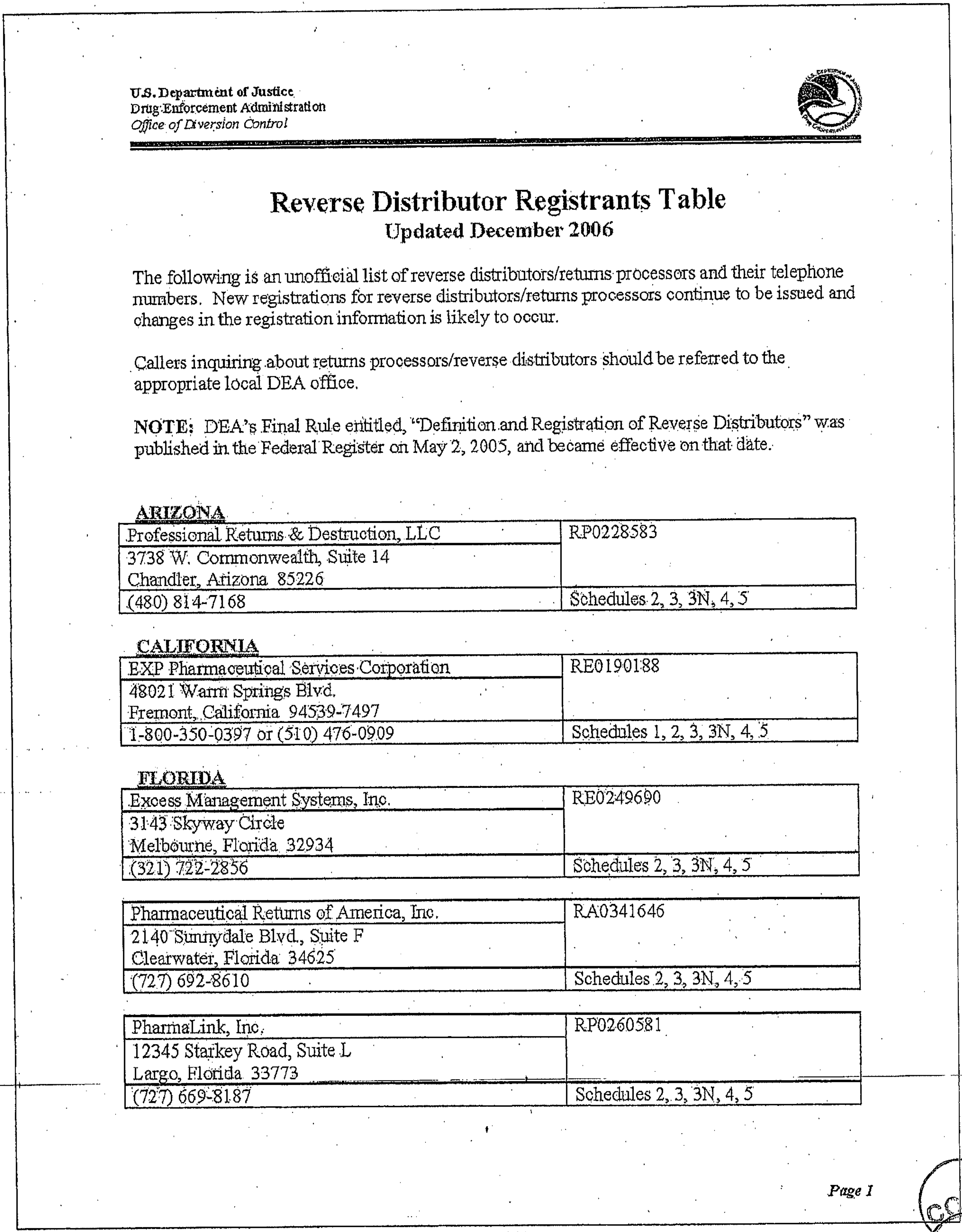
Signature: ________________________________ Date: ______________
(Pharmacist-In-Charge)

Attachment 3

EXPIRED CHEMICAL LOG
(CII)

Drug Name	Lot Number	Expiration Date	Approximate Weight	Reason for Disposal**

Attachment 4



U.S. Department of Justice
Drug Enforcement Administration
Office of Diversion Control

Reverse Distributor Registrants Table

Updated December 2006

The following is an unofficial list of reverse distributors/returns processors and their telephone numbers. New registrations for reverse distributors/returns processors continue to be issued and changes in the registration information is likely to occur.

Callers inquiring about returns processors/reverse distributors should be referred to the appropriate local DEA office.

NOTE: DEA's Final Rule entitled, "Definition and Registration of Reverse Distributors" was published in the Federal Register on May 2, 2005, and became effective on that date.

ARIZONA

Professional Returns & Destruction, LLC	RP0228583
3738 W. Commonwealth, Suite 14 Chandler, Arizona 85226	
(480) 814-7168	Schedules 2, 3, 3N, 4, 5

CALIFORNIA

EXP Pharmaceutical Services Corporation	RE0190188
48021 Warm Springs Blvd. Fremont, California 94539-7497	
1-800-350-0397 or (510) 476-0909	Schedules 1, 2, 3, 3N, 4, 5

FLORIDA

Excess Management Systems, Inc.	RE0249690
3143 Skyway Circle Melbourne, Florida 32934	
(321) 722-2856	Schedules 2, 3, 3N, 4, 5

Pharmaceutical Returns of America, Inc.	RA0341646
2140 Sunnydale Blvd., Suite F Clearwater, Florida 34625	
(727) 692-8610	Schedules 2, 3, 3N, 4, 5

PharmaLink, Inc.	RP0260581
12345 Starkey Road, Suite L Largo, Florida 33773	
(727) 669-8187	Schedules 2, 3, 3N, 4, 5

FLORIDA

Rx Reverse Distributors, Inc.	RR0328131
100B Industrial Park Boulevard Sebastian, Florida 32958	
(772) 388-1212	Schedules 2, 3, 3N, 4, 5

Pharmacy Returns Logistics	RP0331669
27059 83rd Place P.O. Box 391 Branford, Florida 32008	
(386) 935-0876	Schedules 2, 2N, 3, 3N, 4, 5

SAI Transport	RS0182763
3420 Youngs Ridge Road Lakeland, Florida 33810	
(863) 858-7110	Schedules 2, 3, 3N, 4, 5

Stericycle, Inc.	RS0323888
3800 S. Congress Avenue, Suite 8 Boynton Beach, Florida 33426-8424	
1-800-474-9090 or (561) 509-2050	Schedules 2, 3, 3N, 4, 5

GEORGIA

Maximum Rx Credit, Inc.	RM0224749
4765 Stone Mountain Highway, SW, Suite C Lilburn, Georgia 30047	
(770) 985-2136	Schedules 2, 3, 3N, 4, 5

Return Logistics International Corporation	RE0215675
22 Artley Road Savannah, Georgia 31408	
(912) 748-5100	Schedules 1, 2, 3, 3N, 4, 5

Strong Pharmaceutical Services	RS0239219
6264 Crooked Creek Road, Suite 11 Norcross, Georgia 30092	
1-800-778-7664 or (770) 409-1500	Schedules 1, 2, 3, 3N, 4, 5

Universal Rx Solutions of Georgia	RP0242569
2084-900 Lake Industrial Court Conyers, Georgia 30013	
1-800-777-6565 or (770) 785-9710	Schedules 1, 2, 3, 3N, 4, 5

ILLINOIS

Inventory Management Corp. 837 N. Lombard Street Elmhurst, Illinois 60126	RI0301743
(630) 941-1752	Schedules 2, 2N, 3, 3N, 4, 5

Pharma Logistics, Ltd. 1050 East High Street Mundelein, Illinois 60060	RP0225107
1-888-729-7427 or (847) 837-1224	Schedules 2, 3, 3N, 4, 5

Pharmaceutical Returns Services 110 Oak Street North Aurora, Illinois 60542-1109	RP0194174
1-800-215-5878 or (630) 892-8740	Schedules 2, 3, 3N, 4, 5

Progressive Returns, Inc. 6209 W. Grand Chicago, Illinois 60639	RP0215512
(773) 622-9584	Schedules 3, 3N, 4, 5

Stericycle, Inc. 28161 North Keith Drive Lake Forest, Illinois 60045	RS0311035
(847) 607-2008	Schedules 2, 3, 3N, 4, 5

INDIANA

Med-Turn, Inc. 17406 Tiller Court, Suite 1800 Westfield, Indiana 46074	RM0209165
1-800-488-5735	Schedules 2, 3, 3N, 4, 5

Stericycle, Inc. 2670 Executive Drive, Suite A Indianapolis, Indiana 46241	RS0331607
(317) 860-1200	Schedules 2, 3, 3N, 4, 5

IOWA

National Pharmaceutical Returns, Inc. 4164 NW Urbandale Drive Urbandale, Iowa 50322	RN0205408
1-800-470-7725 or (515) 252-7722	Schedules 1, 2, 2N, 3, 3N, 4, 5

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MICHIGAN

Drug and Laboratory Disposal, Inc.	RD0284048
331 Broad Street Plainwell, Michigan 49080-1478	
1-800-685-9824 or (269) 685-9824	Schedules 1, 2, 2N, 3, 3N, 4, 5

MINNESOTA

Pharmaceutical Returns	RP0265593
200 Division Street, Suite 170 Northfield, Minnesota 55057	
1-800-440-0613	Schedules 2, 3, 3N, 4, 5

MISSOURI

Guaranteed Returns Midwest GRX Holding, LLC **dba Guaranteed Returns Midwest**	RE0303230
100 Teduke Court St. Charles, Missouri 63301	
1-800-729-3279 or (636) 724-0044	Schedules 1, 2, 2N, 3, 3N, 4, 5

Logistical Resource Solutions, Inc.	RL0341595
1717 Olive, 4th Floor St. Louis, Missouri 63103	
(314) 241-5771	Schedules 3, 3N, 4, 5

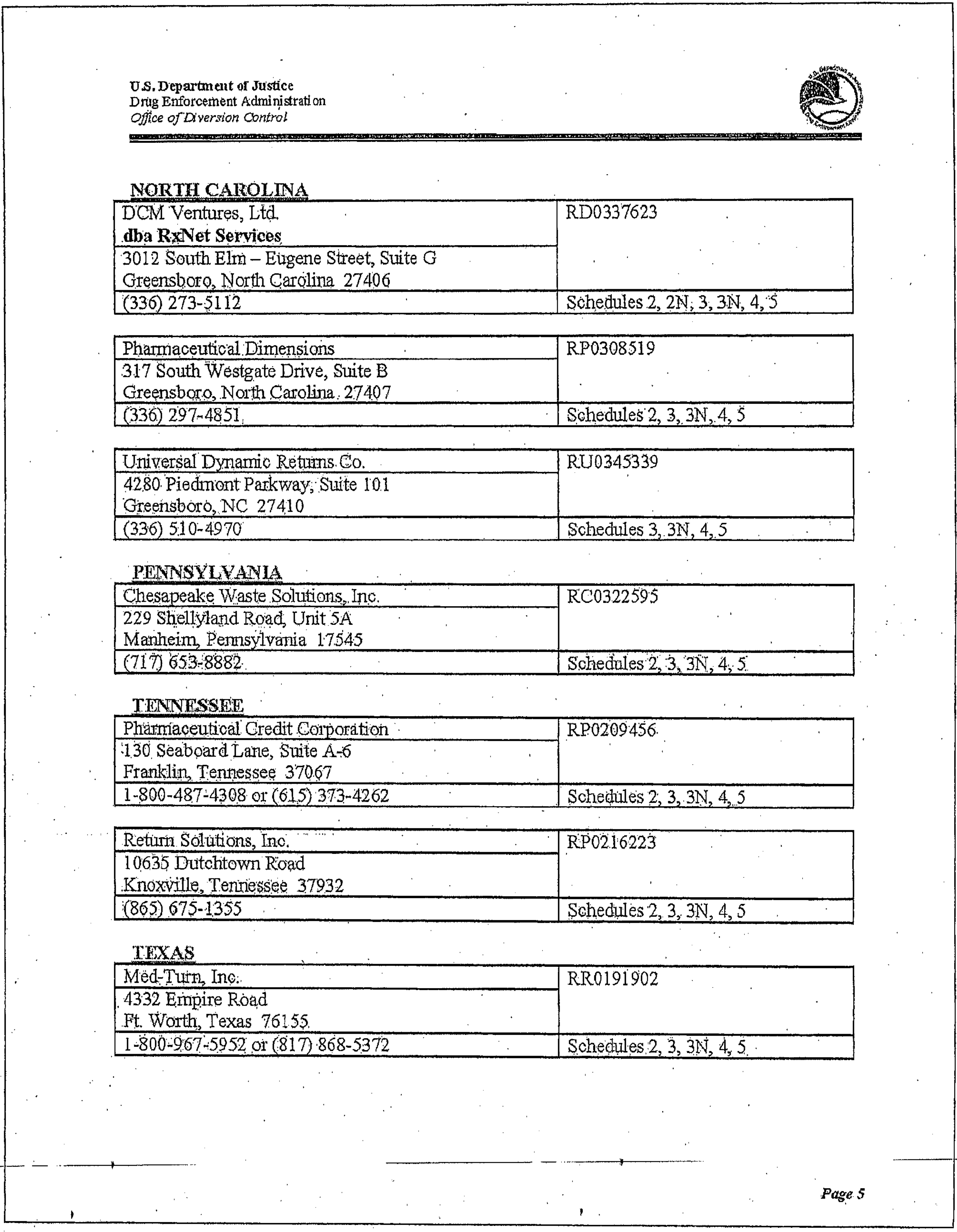
NEW JERSEY

USI of NJ, LP	RB0248701
Munsonhurst Road Complex Franklin, New Jersey 07416	
1-800-321-7388 or (770) 785-9710	Schedules 2, 3, 3N, 4, 5

NEW YORK

Devos, Ltd. **dba Guaranteed Returns**	RD0188311
100 Colin Drive Holbrook, New York 11741	
1-800-473-2138 or (631) 689-0191	Schedules 2, 2N, 3, 3N, 4, 5

Reliable Rx Returns, Inc.	RR0240630
65 Knickerbocker Avenue, Suite C Bohemia, New York 11716	
1-800-215-0727 or (631) 589-4249	Schedules 2, 3, 3N, 4, 5



NORTH CAROLINA

DCM Ventures, Ltd. **dba RxNet Services**	RD0337623
3012 South Elm – Eugene Street, Suite G Greensboro, North Carolina 27406	
(336) 273-5112	Schedules 2, 2N, 3, 3N, 4, 5

Pharmaceutical Dimensions	RP0308519
317 South Westgate Drive, Suite B Greensboro, North Carolina 27407	
(336) 297-4851	Schedules 2, 3, 3N, 4, 5

Universal Dynamic Returns Co.	RU0345339
4280 Piedmont Parkway, Suite 101 Greensboro, NC 27410	
(336) 510-4970	Schedules 3, 3N, 4, 5

PENNSYLVANIA

Chesapeake Waste Solutions, Inc.	RC0322595
229 Shellyland Road, Unit 5A Manheim, Pennsylvania 17545	
(717) 653-8882	Schedules 2, 3, 3N, 4, 5

TENNESSEE

Pharmaceutical Credit Corporation	RP0209456
130 Seaboard Lane, Suite A-6 Franklin, Tennessee 37067	
1-800-487-4308 or (615) 373-4262	Schedules 2, 3, 3N, 4, 5

Return Solutions, Inc.	RP0216223
10635 Dutchtown Road Knoxville, Tennessee 37932	
(865) 675-1355	Schedules 2, 3, 3N, 4, 5

TEXAS

Med-Turn, Inc.	RR0191902
4332 Empire Road Ft. Worth, Texas 76155	
1-800-967-5952 or (817) 868-5372	Schedules 2, 3, 3N, 4, 5

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UTAH

Clean Harbor Aragonite, LLC	RC0331049
11600 North Aptus Road Aragonite, Utah 84029-1339	
(801) 323-8138	Schedules 1, 2, 3, 3N, 4, 5

MD Returns	RM0255807
P.O. Box 526056 1323 W. 7900 S., Suite #206 West Jordan, Utah 84088	
(801) 562-2498	Schedules 2, 3, 3N, 4, 5

National Products Sales, Inc. Pharmaceutical Division	RA0188006
1600 Empire Road Salt Lake City, Utah 84104	
(801) 972-4132	Schedules 2, 3, 3N, 4, 5

WASHINGTON

P.S. Industries, Inc.	RP0203618
1100 2nd Avenue, Suite B1 Seattle, Washington 98101-3425	
(206) 749-0739	Schedules 2, 3, 3N, 4, 5

WISCONSIN

Capital Returns, Inc.	RS0230778
6101 N. 64th Street Milwaukee, Wisconsin 53218	
1-800-950-5479 or (414) 967-2800	Schedules 2, 3, 3N, 4, 5

Veolia ES Technical Solutions, LLC	RV0302389
W124 N9451 Boundary Road Menomonee Falls, Wisconsin 53051	
(262) 255-6655	Schedules 2, 3, 3N, 4, 5

Walgreen Co. **dba Walgreens**	RW0340757
6464 Blanchars Crossing Windsor, Wisconsin 53598-9650	
(847) 315-4412	Schedules 3, 3N, 4, 5

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Attachment 5

DRUG DISPOSAL LOG
(CII)

Drug Name	Lot Number	Expiration Date	Number of Vials	Reason for Disposal**

3/19/08

Attachment 6

OMB Approval No. 1117-0007

U. S. Department of Justice - Drug Enforcement Administration

REGISTRANTS INVENTORY OF DRUGS SURRENDERED

PACKAGE NO.

The following schedule is an inventory of controlled substances which is hereby surrendered to you for proper disposition, per your approval.

FROM: *(Include Name, Street, City, State and ZIP Code in space provided below.)*

Signature of applicant or authorized agent

Registrant's DEA Number

Registrant's Telephone Number

NOTE: REGISTERED MAIL (Return Receipt Requested) IS REQUIRED FOR SHIPMENTS OF DRUGS VIA U. S. POSTAL SERVICE.

	NAME OF DRUG OR PREPARATION Registrants will fill in Columns 1,2,3, and 4 ONLY.	Number of Containers	CONTENTS *(Number of grams, tablets, ounces or other units per container)*	Controlled Substance Content, *(Each Unit)*	FOR DEA USE ONLY		
					DISPOSITION	QUANTITY	
						GMS.	MGS.
	1	2	3	4	5	6	7
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
11							
12							
13							
14							
15							
16							

FORM DEA-41 (8-02) *Previous editions are obsolete*
Electronic Forms Version Designed in JetForm 5.2 Version

See Instructions on reverse (page 2) of form.

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(6-02) Pg. 2

NAME OF DRUG OR PREPARATION Registrants will fill in Columns 1,2,3, and 4 ONLY.	Number of Containers	CONTENTS *(Number of grams, tablets, ounces or other units per container)*	Controlled Substance Content, *(Each Unit)*	FOR DEA USE ONLY		
				DISPOSITION	QUANTITY	
					GMS.	MGS.
1	*2*	*3*	*4*	*5*	*6*	*7*
17						
18						
19						
20						
21						
22						
23						
24						

The controlled substances surrendered in accordance with Title 21 of the Code of Federal Regulations, Section 1307.21, have been received in _______ packages purporting to contain the drugs listed on this inventory and have been: ** (1) Forwarded tape-sealed without opening; (2) Destroyed as indicated and the remainder forwarded tape-sealed after verifying contents; (3) Forwarded tape-sealed after verifying contents.

DATE ______________________ DESTROYED BY: ______________________

** *Strike out lines not applicable.*

WITNESSED BY: ______________________

INSTRUCTIONS

1. DO NOT SEND DRUGS TO ANY DRUG ENFORCEMENT ADMINISTRATION (DEA) OFFICE WITHOUT PRIOR WRITTEN APPROVAL.. Drugs are to be destroyed by : (1) shipment to a reverse distributor registered by DEA (may not require the use of this form): (2) the registrant, according to state and local laws, rules and regulations; or (3) the specific instructions of your area Drug Enforcement Administration Office.
2. List the name of the drug in column 1, the number of containers in column 2, the size of each container in column 3, and in column 4 the controlled substance content of each unit described in column 3; e.g., morphine sulfate tabs., 3 pkgs., 100 tabs., 1/4 gr. (16 mg.) or morphine sulfate tabs., 1 pkg., 83 tabs., 1/2 gr. (32mg.), etc.
3. All packages included on a single line should be identical in name, content and controlled substance strength.

PRIVACY ACT INFORMATION

AUTHORITY: Section 307 of the Controlled Substances Act of 1970 (PL 91-513).
PURPOSE: To document the surrender of controlled substances for disposal.
ROUTINE USES: This form is required by Federal Regulations for the surrender of Controlled Substances. Disclosures of information from this system are made to the following categories of users for the purposes stated.
A. Other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.
B. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.
EFFECT: Failure to document the surrender of unwanted Controlled Substances may result in prosecution for violation of the Controlled Substances Act.

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a Collection of Information unless it displays a valid OMB control number. The valid OMB control number for this Collection of Information is 1117-0007. The time required to complete this information collection is estimated to average 30 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection.

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Attachment 7

U.S. Department of Justice
Drug Enforcement Administration

REPORT OF THEFT OR LOSS OF CONTROLLED SUBSTANCES

Federal Regulations require registrants to submit a detailed report of any theft or loss of Controlled Substances to the Drug Enforcement Administration.

Complete the front and back of this form in triplicate. Forward the original and duplicate copies to the nearest DEA Office. Retain the triplicate copy for your records. Some states may also require a copy of this report.

OMB APPROVAL
No. 1117-0001

1. Name and Address of Registrant (Include ZIP Code)

ZIP CODE ☐☐☐☐☐

2. Phone No. (Include Area Code)

3. DEA Registration Number

2 ltr. prefix ☐☐ 7 digit suffix ☐☐☐☐☐☐☐

4. Date of Theft or Loss

5. Principal Business of Registrant (Check one)

1 ☐ Pharmacy
2 ☐ Practitioner
3 ☐ Manufacturer
4 ☐ Hospital/Clinic
5 ☐ Distributor
6 ☐ Methadone Program
7 ☐ Other (Specify)

6. County in which Registrant is located

7. Was Theft reported to Police? ☐ Yes ☐ No

8. Name and Telephone Number of Police Department (Include Area Code)

9. Number of Thefts or Losses Registrant has experienced in the past 24 months

10. Type of Theft or Loss (Check one and complete items below as appropriate)

1 ☐ Night break-in
2 ☐ Armed robbery
3 ☐ Employee pilferage
4 ☐ Customer theft
5 ☐ Other (Explain)
6 ☐ Lost in transit (Complete Item 14)

11. If Armed Robbery, was anyone:

Killed? ☐ No ☐ Yes (How many) ________
Injured? ☐ No ☐ Yes (How many) ________

12. Purchase value to registrant of Controlled Substances taken?

$

13. Were any pharmaceuticals or merchandise taken?

☐ No ☐ Yes (Est. Value)

$

14. IF LOST IN TRANSIT, COMPLETE THE FOLLOWING:

A. Name of Common Carrier

B. Name of Consignee

C. Consignee's DEA Registration Number

D. Was the carton received by the customer? ☐ Yes ☐ No

E. If received, did it appear to be tampered with? ☐ Yes ☐ No

F. Have you experienced losses in transit from this same carrier in the past? ☐ No ☐ Yes (How many) ________

15. What identifying marks, symbols, or price codes were on the labels of these containers that would assist in identifying the products?

16. If Official Controlled Substance Order Forms (DEA-222) were stolen, give numbers.

17. What security measures have been taken to prevent future thefts or losses?

PRIVACY ACT INFORMATION

AUTHORITY: Section 301 of the Controlled Substances Act of 1970 (PL 91-513).
PURPOSE: Report theft or loss of Controlled Substances.
ROUTINE USES: The Controlled Substances Act authorizes the production of special reports required for statistical and analytical purposes. Disclosures of information from this system are made to the following categories of users for the purposes stated:

A. Other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.
B. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.

EFFECT: Failure to report theft or loss of controlled substances may result in penalties under Section 402 and 403 of the Controlled Substances Act.

In accordance with the Paperwork Reduction Act of 1995, no person is required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this collection of information is 1117-0001. Public reporting burden for this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

FORM DEA-106 (11-00) *Previous editions obsolete*
Electronic Form Version Designed in JetForm 5.2 Version

CONTINUE ON REVERSE

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LIST OF CONTROLLED SUBSTANCES LOST

Name of Substance or Preparation	Name of Controlled Substance in Preparation	Dosage Strength and Form	Quantity
es: Desoxyn	Methamphetamine Hydrochloride	5 mg Tablets	3 x 100
Demerol	Meperidine Hydrochloride	50 mg/ml Vial	5 x 30 ml
Robitussin A-C	Codeine Phosphate	2 mg/cc Liquid	12 Pints
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I certify that the foregoing information is correct to the best of my knowledge and belief.

Signature	Title	Date

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TITLE: PRODUCT PROCUREMENT, RECEIPT AND INSPECTION	
SOP NUMBER: 6.010	**VERSION NUMBER: 7.0**
Non-Sterile and Sterile Laboratory	Effective Date 07/11/11
Originator:	
Reviewer:	

1.0 PURPOSE

1.1 The purpose of this procedure is to establish requirements for product procurement, receipt and inspection.

2.0 SCOPE

2.1 This procedure applies to all components as defined in USP <795>/<797> and all packaging components.

3.0 RESPONSIBILITY

3.1 Quality Control is responsible for approving or rejecting all components, drug product containers, closures and labeling.

4.0 REFERENCES

4.1 USP Current Version <795> "Pharmaceutical Compounding – Non-Sterile Preparations"

4.2 USP Current Version <797> "Pharmaceutical Compounding – Sterile Preparations"

4.3 USP Current Version <1075> "Good Compounding Practices"

4.4 SOP 9.060 "Product Quarantine, Storage and Release"

5.0 DEFINITIONS

5.1 MSDS – Material Safety Data Sheet

5.2 C of A - Certificate of Analysis

5.3 PO – Purchase Order

6.0 FREQUENCY

6.1 Each shipment of components received

7.0 EQUIPMENT & SUPPLIES

7.2 N/A

8.0 GENERAL INFORMATION

8.1 N/A

9.0 PROCEDURE

9.1 No components may be utilized that have been pulled or withdrawn from the market for safety reasons. The Food and Drug Administration will provide, in the form of a "Negative List," all medication recalls.

9.2 Orders placed directly by the compounding staff with a vendor will have a PO# that is generated by using a date of order and the initials of staff member placing the order.

9.3 All orders placed by the compounding staff utilize either the suppliers order form or an internal phone order form (Attachment 1).

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9.4 Order ingredients and components

9.4.1 It is preferable to utilize official USP or NF articles for non-sterile/sterile active ingredients, added substances or excipients.

9.4.2 When non-official ingredients are used, certificates of analysis from their supplier shall accompany the ingredients.

9.5 Component receipt and inspection

9.5.1 Upon receipt of an order, locate original order and, PO# (if applicable).

9.5.2 Visual Inspection

9.5.2.1 Upon receipt of each shipment, compare the shipment against the packing list, and verify PO# on invoice/against the order form.

9.5.2.2 Verify each lot of product for defects of the shipping containers

9.5.2.2.1. No holes, tears, water damage, crushed boxes

9.5.2.2.2. Labeling on the shipping case should match the packing list.

9.5.2.3 If the shipment is acceptable indicate on the packing list "ok", initial and date

9.5.2.4 All bulk chemical shipments must contain a C of A and MSDS. If not included, obtain online or contact supplier if not available online.

9.5.2.5 Verify expiration dates of each chemical received. Contact vendor if expiration date is less than one year and is unlikely that it will be utilized by the expiration date.

9.5.3 Component Identification

9.5.3.1 If the component is acceptable for use the component can be released and should be moved to the proper storage location.

9.5.3.1.1. If the component is not acceptable for use, contact supplier. *NOTE:* Identify the component as "damaged" and either return to the supplier or log and dispose of product into the appropriate waste receptacle.

9.6 Component Storage

9.6.1 Proper handling of material shall be determined according to the hazard code indicated on the product label (acquire appropriate MSDS information).

9.6.2 Storage requirements of the material must follow the guidelines on the product label (i.e. – Refrigeration, Flammable, Caustic...).

9.6.3 All chemicals intended for compounded sterile preparations shall be kept in a designated area and shall be utilized solely for the purpose of sterile compounding.

9.6.4 If the chemical/product is needed for compounding non-sterile preparations, a second container shall be utilized.

9.6.5 All components must be stored off the floor and in a manner to prevent contamination.

10.0 ATTACHMENTS

10.1 Attachment 1 – Phone Order Form

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11.0 HISTORY

Version Number	Date Effective	Description of Change	Change Request Number
1.0	03-08-06	New SOP	CR06030
2.0	N/A	Added visual inspection section 9.5 and component identification section 9.6. Also general procedural clarification. Added Attachment 10.1.	CR06054
3.0	06-16-06	Logo update and N/A boxes added to attachment 1	CR06065
4.0	07-21-06	Short dated and backordered items checkbox added. Form added for verbal and phone orders.	CR06066 &7
5.0	10-10-06	Backordered changed to missing and reason added.	CR06068
6.0	10-24-07	Updating internal PO system	CR07017
7.0	07/11/11	Update internal receiving, delete attachment1, no longer needed	CR11007

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Phone Order Form

Date: ____________________ **P.O. #** ____________________

Vendor: ____________________ **Customer #:** ____________________

Ordered By: ____________________ **Phone #:** ____________________

Quantity: ____

Description:

Conformation #: ____________________

Shipping Method (circle) Next Day 2nd Day Ground

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TITLE: PRODUCT LABELING	
SOP NUMBER: 6.020	**VERSION NUMBER: 3.0**
Non-Sterile and Sterile Laboratory	Effective Date 10/23/07
Originator:	
Reviewer:	

1.0 PURPOSE

1.1 The purpose of this procedure is to establish labeling requirements for compounded products.

2.0 SCOPE

2.1 This procedure applies to all compounding personnel at New England Compounding Center.

3.0 RESPONSIBILITY

3.1 The Pharmacist-in-charge shall supervise this procedure and document that all personnel responsible for compounding will comply with this procedure.

4.0 REFERENCES

4.1 USP Current Version <795> “Pharmaceutical Compounding – Non-Sterile Preparations”

4.2 USP Current Version <797> “Pharmaceutical Compounding – Sterile Preparations”

4.3 USP Current Version <1075> “Good Compounding Practices”

4.4 SOP 9.050 “Beyond-Use Dating (BUD) of Compounded Preparations”

5.0 DEFINITIONS

5.1 BUD – Beyond-use date

6.0 FREQUENCY

6.1 N/A

7.0 EQUIPMENT & SUPPLIES

7.1 Label stock

8.0 GENERAL INFORMATION

8.1 N/A

9.0 PROCEDURE

9.1 Products prepared in anticipation of a prescription shall be labeled with the following items:

- 9.1.1 Name and address of compounding pharmacy
- 9.1.2 Name of compounded preparation, or a complete list of active ingredients
- 9.1.3 A reference or established name, or a distinct common name
- 9.1.4 Dosage form and potency
- 9.1.5 Volume
- 9.1.6 Batch/lot number
- 9.1.7 Assigned BUD
- 9.1.8 Bar code, if required
- 9.1.9 Storage requirements, if frozen or refrigerated
- 9.1.10 Special handling note – i.e. preservative free, single use, need for dilution

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9.2 Prescription labels shall include the following information:

- 9.2.1 Name and address of the compounding pharmacy
- 9.2.2 Patient's name
- 9.2.3 Prescriber's name
- 9.2.4 Prescription number
- 9.2.5 A reference or established name, or a distinct common name
- 9.2.6 Dosage form and potency
- 9.2.7 Statement of quantity (total volume)
- 9.2.8 Directions for use including appropriate routes of administration
- 9.2.9 Date prescription filled
- 9.2.10 Assigned BUD
- 9.2.11 The initials of the compounder who prepared the label
- 9.2.12 Storage requirements, including appropriate temperature ranges and protect from light
- 9.2.13 Auxiliary labels (if applicable)
- 9.2.14 Any other items required by state or federal law

9.3 Compounded preparations must have a listing of the names and amounts or concentrations of active ingredients.

9.4 Copies of the prescription label, if an outpatient prescription, and the product label shall be made and attached to the compounding record.

9.5 The compounder shall visually inspect the product for correct labeling after completion of the compounding process. Visual inspection should be documented on the formulation record, by checking and initialing the sample label on the compounding record.

10.0 ATTACHMENTS

N/A

11.0 HISTORY

Version Number	Date Effective	Description of Change	Change Request Number
1.0	03/08/06	New SOP	CR06031
2.0	04/11/06	Clarification in steps 9.7 and 9.8 that all labels are verified and documented.	CR06055
3.0	10/23/07	Minor updates	CR07009

10-23-07

TITLE: HANDLING OF CYTOTOXIC DRUG COMPOUNDS

SOP NUMBER: 7.010 **VERSION NUMBER: 1.0**

Non-Sterile and Sterile Laboratory Effective Date 03-08-06

Originator:

Reviewer:

1.0 PURPOSE

1.1 The purpose of this procedure is to establish guidelines for safe handling of cytotoxic drugs.

2.0 SCOPE

2.1 This procedure applies to all cytotoxic compounding personnel at New England Compounding Center.

3.0 RESPONSIBILITY

3.1 The Pharmacist-in-charge shall supervise this procedure or document that another staff member has been designated to complete the task.

4.0 REFERENCES

4.1 SOP 5.050 "Delivery of Compounded Preparations"

4.2 SOP 7.020 "Disposing of Cytotoxic Drug Waste"

4.3 SOP 7.030 "Cytotoxic Drug Spills"

5.0 DEFINITIONS

5.1 BSC – Biological Safety Cabinet

5.2 NIOSH – National Institute for Occupational Safety and Health

5.3 MSDS – Material Safety Data Sheet

6.0 FREQUENCY

6.1 This procedure must be followed each time a cytotoxic product is handled or compounded.

6.2 The BSC shall be certified by an outside consulting agency biannually.

7.0 EQUIPMENT & SUPPLIES

7.1 BSC

7.2 Rotating germicide

7.3 Gowns/gloves

7.4 Mask/NIOSH-approved respirator

7.5 Cytotoxic drug spill kit

7.6 MSDS file

7.7 Validation of personnel for proper garb procedures - drug compounding

8.0 GENERAL INFORMATION

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8.1 Glove boxes are not suitable for compounding or handling cytotoxic preparations. These preparations shall only be handled in BSCs.

8.2 The blower unit on the BSC should remain on at all times.

9.0 PROCEDURE

9.1 All cytotoxic compounding personnel shall wear the following items to shield themselves from possible contact with the cytotoxic product and prevent contamination:

- 9.1.1 Jumpsuit or Frock with front closure, long sleeves and elastic bands
- 9.1.2 Safety glasses or goggles
- 9.1.3 At least one pair (often times two pairs) of powder-free, latex or nitrile gloves
- 9.1.4 Bouffant
- 9.1.5 Mask
- 9.1.6 Booties

9.2 When using two pairs of gloves, one pair shall be tucked under the elastic wristbands and the second pair shall be pulled over the top of the elastic wristbands. Gloves must be changed immediately upon contamination.

9.3 All personnel handling cytotoxic drugs shall be validated for proper garb procedures after training is completed, and before any compounding of cytotoxic drugs is performed.

9.4 Cytotoxic drugs shall be prepared in a BSC and certified by an outside consulting agency at least once every six months.

- 9.4.1 All compounding personnel and individuals contracted to work in a BSC should be notified that cytotoxic drugs are compounded within the BSC.
- 9.4.2 The blower unit on the BSC should remain on at all times.

9.5 Cytotoxic drug spills shall be handled immediately. Refer to SOP 7.030, "Cytotoxic Drug Spills." Any contaminated garb shall be disposed of immediately.

9.6 Sharps containers, clearly marked "For Cytotoxic Drugs Only," shall be used for any sharps that are used during the compounding process and shall be disposed of properly when full.

9.7 All cytotoxic compounds shall be stored in a controlled environment with proper temperature and humidity ranges as specified by the manufacturers label for product stability.

9.8 The finished product shall be labeled within the clean room and sealed in an appropriate container (zip lock bag….etc). Clearly labeled as"Cytotoxic Product", prior to leaving the clean room.

10.0 ATTACHMENTS

10.1 N/A

11.0 HISTORY

Version Number	Date Effective	Description of Change	Change Request Number
1.0	03-08-06	New SOP	CR06032

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TITLE: DISPOSING OF CYTOTOXIC DRUG WASTE
SOP NUMBER: 7.020 **VERSION NUMBER:** 1.0
Non-Sterile and Sterile Laboratory Effective Date 03-08-06
Originator:
Reviewer:

1.0 PURPOSE

1.1 The purpose of this procedure is to establish guidelines for the disposal of cytotoxic drugs.

2.0 SCOPE

2.1 This procedure applies to all cytotoxic compounding personnel at New England Compounding Center.

3.0 RESPONSIBILITY

3.1 The Pharmacist-in-charge shall supervise this procedure or document that another staff member has been designated to complete the task.

4.0 REFERENCES

4.1 Local, State and Federal laws

5.0 DEFINITIONS

5.1 N/A

6.0 FREQUENCY

6.1 When disposing of any cytotoxic drug product.

7.0 EQUIPMENT & SUPPLIES

7.1 Cytotoxic drug disposal containers

7.2 Cytotoxic sharps containers

7.3 Contract vendor for incineration of discarded cytotoxic drug products

8.0 GENERAL INFORMATION

8.1 Disposal of cytotoxic drug products must comply with all applicable local, state, and federal requirements.

9.0 PROCEDURE

9.1 Use gloves when handling cytotoxic waste containers.

9.2 All waste containers shall be stored in a low-traffic area.

9.3 Cytotoxic drug products must be disposed of separately from other drug products. Do not place regular trash in cytotoxic drug waste containers.

9.4 Cytotoxic drug disposal containers shall be clearly labeled "For Cytotoxic Drugs Only."

9.5 A designated sharps container, clearly labeled "For Cytotoxic Drugs Only," shall be used to dispose of any needles or broken glass generated during the compounding of cytotoxic drugs.

9.6 Protective garb must be disposed of properly.

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9.6.1 To safely remove protective apparel, the outer pair of gloves shall be removed first, the gown shall be removed next and the inner pair of gloves shall be removed last.

9.7 When the gloves are removed, pull them off inside out, so that the outside of the gloves do not touch the skin. The gown and gloves shall be properly discarded.

9.8 A licensed vendor shall dispose of the cytotoxic hazardous drug containers. Proper documentation of the pickup and incineration of the containers shall be retained in a file as proof of proper disposal of cytotoxic drug waste.

10.0 ATTACHMENT

10.1 N/A

11.0 HISTORY

Version Number	Date Effective	Description of Change	Change Request Number
1.0	03-08-06	New SOP	CR06033

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TITLE: CYTOTOXIC DRUG SPILLS	
SOP NUMBER: 7.030	**VERSION NUMBER: 1.0**
Non-Sterile and Sterile Laboratory	Effective Date 03-08-06
Originator:	
Reviewer:	

1.0 PURPOSE

1.1 The purpose of this procedure is to establish guidelines for the handling of cytotoxic drug spills in a safe and efficient manner.

2.0 SCOPE

2.1 This procedure applies to all cytotoxic compounding personnel at New England Compounding Center.

3.0 RESPONSIBILITY

3.1 The Pharmacist-in-charge shall supervise this procedure or document that another staff member has been designated to complete the task.

4.0 REFERENCES

4.1 Local, State and Federal laws

4.2 SOP 5.020 "Patient Satisfaction"

5.0 DEFINITIONS

5.1 MSDS – Material Safety Data Sheet

5.2 NIOSH – National Institute for Occupational Safety and Health

5.3 BSC – Biological Safety Cabinet

6.0 FREQUENCY

6.1 Whenever a cytotoxic drug spill occurs

7.0 EQUIPMENT & SUPPLIES

7.1 Cytotoxic drug spill kit

7.2 Cytotoxic drug disposal containers

7.3 Cytotoxic sharps container

7.4 MSDS file

7.5 Cytotoxic drug spill "Caution" sign

7.6 Detergent solution

8.0 GENERAL INFORMATION

8.1 All cytotoxic drug spills shall be handled immediately.

9.0 PROCEDURE

9.1 All Cytotoxic drug spills shall be cleaned up immediately and appropriately. Personnel involved in the spill shall be given priority, and the spill shall be contained to the immediate vicinity of the spill.

9.2 A Cytotoxic drug spill kit shall be present in the cytotoxic compounding area. A cytotoxic drug spill kit shall contain the following items:

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- 9.2.1 Gown-1 maximum protection poly-coated - blue, xx-large
- 9.2.2 Latex Free Gloves – 2 pairs, 8mil, medium
- 9.2.3 Mask – 1 dust/mist respirator mask
- 9.2.4 Waste bag – 1 (15 gal.)
- 9.2.5 Chemo Bio-wipe™* Bag - 1
- 9.2.6 Goggles - 1

9.3 The three categories of spills discussed in this procedure are:

- 9.3.1 Personnel spills
- 9.3.2 Small spills
- 9.3.3 Large spills

9.4 Personnel Spills

- 9.4.1 If cytotoxic drug products are spilled or splashed onto the garb of compounding personnel, compounding shall immediately cease and the individual shall carry out the decontamination process.
- 9.4.2 The compounding gown and gloves shall be removed immediately and shall be appropriately discarded in a clearly labeled cytotoxic waste container.
- 9.4.3 Hands must be washed thoroughly with soap and water.
- 9.4.4 If protective eyewear is contaminated, the eyewear shall be sprayed with sterile 70% isopropyl alcohol and rinsed with water.
- 9.4.5 If the cytotoxic drug has splashed directly into the eyes, the eyes must be immediately flushed with water or an eye wash solution for at least five minutes.
- 9.4.6 If necessary, seek medical attention immediately.

9.5 Small Spills

- 9.5.1 Small spills are categorized as those less than 5mL or 5g.
- 9.5.2 A cytotoxic drug spill "Caution" sign shall be posted in the cytotoxic compounding area to alert others of the cytotoxic drug spill until decontamination is complete.
- 9.5.3 The individual designated to clean a small spill shall wear a gown, double latex gloves, and chemical splash goggles.
- 9.5.4 If a small spill occurs inside the BSC and the HEPA filter has become contaminated, the unit must be shut down immediately.
    - 9.5.4.1 The BSC cannot be used until it has been properly decontaminated.
    - 9.5.4.2 Only qualified personnel shall remove the HEPA filter grid from the BSC, and they must be forewarned that a cytotoxic agent has contaminated the filter.
    - 9.5.4.3 The unit must be certified by an outside consulting company prior to use.
- 9.5.5 Liquids shall be wiped with dry, absorbent pads, and solids shall be wiped with wet, absorbent pads.
- 9.5.6 All contaminated surfaces shall be thoroughly cleaned three times using a detergent solution followed by clean water.

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9.5.7 Any broken glass fragments shall be picked up using a small scoop (never use hands) and placed in a sharps container that is clearly labeled "For Cytotoxic Drugs Only." The sharps container shall then be placed into a cytotoxic drug disposal bag, along with the used absorbent pads and any other contaminated waste.

9.6 Large Spills

9.6.1 Large spills are categorized as those larger than 5mL or 5g.

9.6.2 When a large spill occurs, the area shall be immediately isolated and aerosol generation shall be avoided.

9.6.3 A cytotoxic drug spill "Caution" sign shall be posted in the cytotoxic compounding area to alert others of the cytotoxic drug spill until decontamination is complete.

9.6.4 The individual designated to clean a small spill shall wear a gown, double latex gloves, and chemical splash goggles.

9.6.5 If a large spill occurs inside the BSC and the HEPA filter has become contaminated, the unit must be shut down immediately.

9.6.5.1 The BSC cannot be used until it has been properly decontaminated.

9.6.5.2 Only qualified personnel shall remove the HEPA filter grid from the BSC, and they must be forewarned that a cytotoxic agent has contaminated the filter.

9.6.5.3 The unit must be certified by an outside consulting company prior to use

9.6.6 Liquids should be covered with absorbent pads, and solids should be covered with damp, absorbent pads. Do not apply chemical inactivators to the absorbed drug as this may produce cytotoxic by-products.

9.6.7 All contaminated surfaces shall be thoroughly cleaned three times using a detergent solution followed by clean water.

9.6.7.1.1 Any broken glass fragments shall be picked up using a small scoop (never use hands) and placed in a sharps container that is clearly labeled "For Cytotoxic Drugs Only." The sharps container shall then be placed into a cytotoxic drug disposal bag, along with the used absorbent pads and any other contaminated waste.

10.0 ATTACHMENTS

10.1 N/A

11.0 HISTORY

Version Number	Date Effective	Description of Change	Change Request Number
1.0	03-08-06	New SOP	CR06034

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TITLE: STERILIZATION AND DEPYROGENATION	
SOP NUMBER: 8.010	**VERSION NUMBER: 2.0**
Authorized By:	Date: 03-30-06 Dept: LAB
Written By: Anne Avezzano	Date: 03-29-06
Reviewed By:	Date: 03-30-06
Date Effective: 04-06-06	

1.0 PURPOSE

1.1 The purpose of this procedure is to outline proper sterilization and depyrogenation methods.

2.0 SCOPE

2.1 This procedure applies to all sterile compounding personnel at New England Compounding Center.

3.0 RESPONSIBILITY

3.1 The Pharmacist-in-charge shall supervise this procedure or document that another staff member has been designated to complete the task.

3.2 The Pharmacist-in-charge shall be responsible for assuring that all personnel involved in generating, completing, or reviewing data are properly trained for this procedure.

3.3 All employees involved in sterilization and depyrogenation at New England Compounding Center are responsible for complying with this procedure.

4.0 REFERENCES

4.1 USP Current Version <797> "Pharmaceutical Compounding – Sterile Preparations"

4.2 USP Current Version <1211> "Sterilization and Sterility Assurance of Compendial Articles"

4.3 PDA "Technical Report No. 3 – Validation of Dry Heat Processes used for Sterilization and Depyrogenation"

4.4 ASHP "Principles of Sterile Product Preparations"

4.5 SOP 9.020 "Good Documentation Practices (GDP)"

5.0 DEFINITIONS

5.1 Sterilization – Validated process to render a product free from viable microorganisms

5.2 Depyrogenation – Process used to destroy or remove pyrogen (endotoxins)

5.3 CSP – Compounded Sterile Preparation

6.0 FREQUENCY

6.1 When preparing a sterile and/or pyrogen free preparation

7.0 EQUIPMENT & SUPPLIES

7.1 Autoclave

7.2 Dry-heat oven

7.3 Appropriate filter

7.4 Appropriate final container

7.5 Compounding log sheet

7.6 Filter integrity tester

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7.7 Filter compatibility chart

8.0 GENERAL INFORMATION

8.1 N/A

9.0 PROCEDURE

9.1 Sterilization Method

9.1.1 The appropriate sterilization technique shall be determined based on the unique properties of the chemicals to be sterilized in order to prevent destruction or modification of the product. The product must be sterilized without compromising the strength, purity, quality, and packaging integrity of the CSP.

9.1.2 General guidelines for matching CSPs and components to appropriate sterilization methods shall include the following:

9.1.2.1 CSPs must be ascertained to remain physically and chemically stable when subjected to the selected sterilization method.

9.1.2.2 If using a sterile, micro-porous membrane filter, personnel shall ascertain from appropriate information sources that the filter used to sterilize the CSP either during compounding or during administration is chemically and physically compatible with the CSP.

9.1.3 The sterilization method chosen for each CSP shall be noted and documented on the formulation record.

9.1.4 The primary sterilization methods include:

9.1.4.1 Filtration sterilization

9.1.4.2 Steam sterilization

9.1.4.3 Dry-heat sterilization

9.2 Filtration Sterilization

9.2.1 Filtration sterilization removes, but does not destroy, microorganisms. Filtration shall be used for solutions that are unstable to other types of sterilization methods.

9.2.2 When filters are selected, these characteristics must be considered:

9.2.2.1 Pore size – Sterilizing filters of 0.22µm or smaller porosity shall be used. In an emergency, a 0.45-µm filter may be used if compositionally identical to a 0.22-µm filter.

9.2.2.2 Compatibility – While membrane filters are compatible with most pharmaceutical solutions, extreme care must be exercised to ensure compatibility. Biological products, alcohols, glycols, and dimethylformamide are examples of products that can result in filter membrane incompatibilities with the CSP.

9.2.3 To provide a practical flow rate of a solution, a filter with the appropriate surface area must be used.

9.2.4 Commercially available sterile filters approved for human use applications in sterilizing pharmaceutical fluids shall be used.

9.2.4.1 The filters must be accompanied by certification from the manufacturer to retain at least 10^7 microorganisms of a strain of *Brevundimonas (Pseudomonas)*

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diminuta on each square centimeter of upstream filter surface under conditions similar to those in which the preparation will be sterilized.

9.2.5 According to USP <797>, filters shall be disposable, sterile, and pyrogen-free, and shall have a nominal porosity of 0.2μm, including filters with a porosity of 0.22μm.

9.2.6 When a CSP is known to have excess particulate matter, a pre-filter of larger porosity membrane shall be placed upstream from the sterilizing filter to remove gross particulate contaminants, so as to maximize the efficiency of the sterilizing filter.

Note: All high-risk preparations must be pre-filtered.

9.2.7 When filter devices are assembled from separate, non-sterile components by compounding personnel, the assembled devices shall be sterilized and shall be ascertained to be effective under relevant conditions before they are used to sterilize CSPs.

9.2.8 An integrity test (bubble test) shall be performed. An observed value of the integrity test lower than the manufacturer's specifications indicates that the filter was defective or ruptured during the sterilization process. The Pharmacist-in-charge shall be notified and will determine whether testing, and/or re-sterilization and/or destruction of the CSP is necessary.

9.2.8.1 To perform an integrity test, first attach the inlet of the filter to the male Luer-Lok connector on the integrity tester assembly.

9.2.8.2 Attach the flexible, plastic end of the sampling tube to the outlet of the filter unit.

9.2.8.3 Connect the syringe plunger to the female Luer-Lok connector of the integrity tester assembly. If the syringe has a Luer-slip connection, hold the syringe onto the assembly at all times during the procedure.

9.2.8.4 Withdraw the syringe plunger to the 50 mL line to fill the syringe with air.

9.2.8.5 Connect the syringe onto the integrity tester assembly. Make sure the end of the sampling tube connected to the filter unit is submerged in water. Gradually push the syringe plunger to increase the pressure on the pressure gauge and filter unit.

9.2.8.6 Continue to increase the pressure until a stream of bubbles starts to come out of the outlet tube (the bubble point). Record the gauge pressure and compare it to the manufacturer's minimum bubble point specifications.

9.2.9 The filter lot number and manufacturer should be documented on the formulation record and subsequent compounding log sheet.

9.3 Steam Sterilization

9.3.1 A steam sterilization cycle shall be verified to ensure sterilization of all CSPs under specified operating conditions and parameters.

9.3.2 Autoclaving should be reserved for items that can be penetrated by water vapor (steam). Dry, sealed containers, oils, and waxes may not be suitable for steam sterilization.

9.3.3 Select the appropriate cycle parameter for the item(s) to be autoclaved.

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9.3.3.1 Dry Goods Cycle – Used for compounding equipment or instruments and glassware

9.3.3.2 Wrapped Goods Cycle – Used for items wrapped in a sterilization bag

9.3.3.3 Liquids Cycle – Used for all liquid items

9.3.4 Monitoring data from each cycle (i.e. a printout of the preset and actual parameters of the cycle) shall be recorded to ensure that the processes are performed properly and that all critical parameters are within specified limits during processing.

9.3.5 To achieve sterility, it is necessary that materials be exposed to steam at 121°C for a minimum of 15 minutes under pressure of about one atmosphere or 15 pounds per square inch (psi).

9.3.6 The temperature and length of exposure shall be documented on the formulation record and subsequent compounding log sheet. All printouts generated from the autoclave should be attached to the formulation record following SOP 9.020, "Good Documentation Practices (GDP)."

9.3.7 Appropriate indicators (biological or chemical) shall be used to verify the effectiveness of steam sterilization.

9.3.8 Plastic, glass, and metal devices must be tightly wrapped in low-particle shedding paper or fabrics, or must be sealed in envelopes that prevent post-sterilization contamination.

9.3.9 Immediately before filling and sealing ampoules/vials to be steam sterilized, solutions shall be passed through a filter having a porosity of no larger than 1.2µm for removal of large, particulate matter.

9.3.10 Prior to steam sterilization, verification of heat labile components must be made to ensure integrity after steam sterilization.

9.3.11 CSPs shall be inspected for any damage that may have occurred during the steam sterilization cycle.

9.4 Dry-Heat Sterilization

9.4.1 Dry-heat oven cycles shall be verified to ensure the sterilization of all CSPs under specified operating conditions and parameters.

9.4.2 Dry-heat sterilization shall be used to sterilize glass, stainless steel, other hard surface materials, and dry powders not labile to high temperatures.

9.4.3 Injectable, oily solutions can be dry-heat sterilized if the active ingredient retains potency and stability.

9.4.4 Validation of dry-heat sterilization of an object depends not only on monitoring temperature but also depends on the use of appropriate biological indicators.

9.4.5 To achieve sterility, the CSP must achieve and maintain a temperature of 170°C for two hours.

9.4.6 The temperature and length of exposure shall be documented on the formulation record and subsequent compounding log sheet.

9.5 Appropriate sterilization methods, exposure times, and temperature settings shall be verified for each CSP.

9.6 Depyrogenation

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9.6.1 The only method available for depyrogenation is dry-heat.

9.6.2 Utensils used in the clean room to measure chemicals and/or raw materials must be depyrogenated after use.

9.6.3 To achieve depyrogenation, as well as sterility, within acceptable units, covered equipment must be exposed to dry heat in an oven at a mean temperature of 250°C for two hours.

9.6.3.1 The load configuration has been defined during verification studies. Large items are required to be loaded in the top, medium and large loaded in the middle and only small items are to be loaded in the bottom of the oven.

9.6.3.2 Glass containers must be double wrapped with foil covering the top and at least 2/3 of the container. Smaller items should be double wrapped completely.

9.6.3.3 Depyrogenated items should be stored in a controlled environment only.

9.6.4 Each cycle run must be documented in the LUMAC.

10.0 ATTACHMENTS

10.1 N/A

11.0 HISTORY

Version Number	Date Effective	Description of Change	Change Request Number
1.0	03-08-06	New SOP.	CR06035
2.0		Added instructions for integrity testing. Depyrogenation load configuration added. Requirement for foil wrapping of glassware added.	CR06060

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6.0 FREQUENCY

6.1 Invariable

7.0 EQUIPMENT & SUPPLIES

7.1 N/A

8.0 GENERAL INFORMATION

8.1 N/A

9.0 PROCEDURE

9.1 SOPs are used to direct routine compounding operations. They provide specific "work instructions" and include attached forms to be used for data recording. SOPs include the responsibilities and duties of personnel.

9.2 SOPs are subject to change as quality system improvements are made and/or regulations are updated. Changes to SOPs will be made according to SOP 1.010, "Policies and Procedures."

9.3 Established SOPs may include, but are not limited to, the following:

9.3.1 Monitoring and Evaluation Activities

9.3.1.1 Environmental Monitoring (EM) – New England Compounding Center shall evaluate the environmental quality of sterile compounding preparation areas by measuring the number of particles and the number of viable microorganisms found within the clean room facility. A written schedule of EM activities shall be prepared and adhered to, including evaluation of all controlled air environmental areas of the facility. The EM program will verify that glove boxes in the sterile preparation room meet Class 10 (ISO Class 4) standards and that surrounding sterile preparation rooms meet Class 1000 (ISO Class 6), Class 10,000 (ISO Class 7) and Class 100,000 (ISO Class 8) standards.

9.3.1.2 Review and Corrective Action – QA program activities generating data, reports or deficiencies will be promptly reviewed by the Pharmacist-in-charge. Other activities subject to review, including EM results, are equipment and process validation, training assessments and continuing education. Prompt follow-up actions shall be initiated when any action limits are exceeded and will be supervised by the compliance control officer and/or the Pharmacist-in-charge.

9.3.2 Microbial Control Activities

9.3.2.1 Personnel Gowning – Staff engaged in both sterile and non-sterile compounding operations, or entering controlled work areas, must properly utilize provided personal protective equipment (PPE). This may include bouffants, booties, coveralls, gowns, masks, and gloves. Each compounding staff member shall be trained on proper gowning requirements.

9.3.2.2 Restricted Access Areas – Access to controlled work areas shall be restricted to qualified personnel with specific responsibilities requiring their presence in the area.

9.3.2.3 Personal Hygiene – Personnel assigned to compounding activities may not wear outer coats or jackets. Makeup and jewelry must not be exposed when compounding sterile preparations. Compounding staff must wash hands and lower arms in automated hand washer and dry them prior to entering controlled work areas or prior to handling

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compounding materials or equipment. Personnel who are ill or have skin lesions shall not engage in compounding operations and shall not enter controlled work areas. Food, drink or similar items shall never be introduced into controlled work areas.

9.3.2.4 Aseptic Technique – All sterile compounding personnel shall employ aseptic technique to assist microbial control. Sterile compounding personnel shall be trained on proper aseptic technique.

9.3.2.5 Compounding Technique – All compounding personnel shall employ good compounding techniques to assist quality control. Compounding personnel shall be trained on proper compounding technique.

9.3.2.6 Cleaning and Sanitizing – Cleaning, sanitizing and organizing of the direct and contiguous compounding areas must be performed as defined in SOP 3.020 and 3.050. Cleaning includes, but is not limited to, the removal of loose materials and residue on work surfaces, carts, shelving and other product contact sites. Cleaning is followed by an application of a residue-free sanitizing agent to assist microbial control. Cleaning agents shall be reviewed and provided by the Pharmacist-in-charge or quality control officer and shall be used in accordance with the manufacturer's directions.

9.3.3 Training and Continuing Education (CE)

9.3.3.1 Each employee shall receive training and CE commensurate with their duties and responsibilities. Personnel involved in compounding, evaluating, packaging and dispensing of product shall be properly trained for the type of compounding conducted. Training should be ongoing and responsive to changes in acceptable pharmaceutical practices and any deficiencies revealed through activities of the QA program.

9.3.4 Quality Process Controls

9.3.4.1 Media Fills – In regards to sterile compounding, media fills shall be performed in accordance with USP <797>.

9.3.4.2 Process Validation – In regards to non-sterile compounding, critical processes shall be validated to ensure that procedures will consistently result in the expected qualities in the finished preparation.

9.3.4.3 Batch Records and Reports – A copy of the prescription, formula and associated production record for compounded preparations will be created and retained. Copies of customer/patient complaints shall be created and retained as well as records of follow-up actions. Reports of adverse events shall be documented and promptly reviewed by the Pharmacist-in-charge and corrective actions taken, as appropriate.

9.3.4.4 Labeling – Labeling of compounded preparations will conform to USP <1075>.

9.3.5 Documentation

9.3.5.1 Compounding shall be performed in accordance with established SOPs specific to individual products and processes.

9.3.5.2 Records of each significant step in the compounding process shall be created and maintained.

9.3.5.3 SOPs and records shall be prepared in accordance with a procedure specific to that function.

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9.3.5.4 SOPs and records shall be stored in a controlled manner and ultimately destroyed by a defined schedule. SOPs and records shall be shredded and not discarded intact.

9.3.5.5 Deviations to SOPs shall be investigated and documented per SOP 1.030.

9.3.6 Facility and Equipment

9.3.6.1 The facility shall be maintained in a manner to minimize and prevent mix-ups between ingredients, containers, labels, in-process materials and finished preparations.

9.3.6.2 Materials for use in the sterile preparation areas should be dedicated whenever possible. Storage of materials not destined for compounding shall be segregated from materials intended for compounding.

9.3.6.3 Interruption of basic utility services, such as water, electricity, plumbing, heat or air conditioning shall be cause for cessation of compounding in all but the most extreme patient need circumstances. Utility interruptions shall be cause for initiation of an investigation to evaluate possible impacts to products and materials in the facility.

9.3.6.4 Equipment used in compounding shall be utilized, calibrated and maintained in accordance with specific SOPs to include incorporation of manufacturer's requirements and recommendations. Calibration and maintenance records shall be maintained for the lifetime of the equipment.

9.3.6.5 Equipment requiring validation to assure repeatable and reliable operation and performance should be defined. Frequency of validation should be determined. Results of equipment validation should be maintained.

9.3.6.6 Equipment employed for compounding shall be inspected, cleaned and validated at appropriate times to ensure the accuracy and reliability of equipment performance is maintained.

9.3.7 Product Complaints

9.3.7.1 The Compliance Officer is responsible for documenting all product complaints and complaints of adverse events in accordance with SOP 5.030

9.3.8 Destruction and Recall

9.3.8.1 Expired, contaminated or otherwise unsuitable compounding preparations or materials shall be immediately removed from compounding preparation areas and stored separately until disposed of.

9.3.8.2 Expired materials shall be labeled or otherwise designated as being unsuitable for use.

9.3.9 Recalls shall be performed in accordance with SOP 9.070.

9.4 The record retention period for all data/documentation is seven years, unless otherwise stated by the Mass State Board of Pharmacy.

9.5 New England Compounding Center must monitor and measure the processes in place and implement necessary action to achieve expected results and to continue to improve the processes.

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10.0 ATTACHMENTS

10.1 N/A

11.0 HISTORY

Version Number	Date Effective	Description of Change	Change Request Number
1.0	03-08-06	New SOP	CR06036
2.0	03-18-08	Minor Updating	CR08009

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TITLE: GOOD DOCUMENTATION PRACTICES (GDP)	
SOP NUMBER: 9.020	**VERSION NUMBER: 3.0**
Non-Sterile and Sterile Laboratory	Effective Date 09-29-08
Originator:	
Reviewer:	

1.0 PURPOSE

1.1 The purpose of this procedure is to define requirements for all documents that affect the acceptability of materials, processes or products.

2.0 SCOPE

2.1 This procedure applies to all personnel at New England Compounding Center.

3.0 RESPONSIBILITY

3.1 The Pharmacist-in-charge shall supervise this procedure or document that another staff member has been designated to complete the task.

3.2 The Pharmacist-in-charge shall be responsible for assuring that all personnel involved in generating, completing or reviewing data are trained in the requirements of this procedure.

3.3 All employees at New England Compounding Center are responsible for complying with this procedure.

4.0 REFERENCES

4.1 N/A

5.0 DEFINITIONS

5.1 GDP - Good Documentation Practices

5.2 Document - Information and its support medium (e.g. compounding records, specifications and reports); used to determine acceptability of materials, equipment, lab instruments, operating parameters, processes or products.

5.3 Quality Record - Original data that is the result of original observation and activity; gives results achieved or provides evidence of activities performed; includes entries made in laboratory notebooks, forms, chart recordings or exact copies thereof.

5.4 Traceability - The ability to retrieve the product compounding history and filling history

5.5 Performed By/Quality Control - Person executing the task and/or recording the data

5.6 Reviewed By – Person who reviews documentation; must be performed by someone with the technical ability to assess acceptability.

6.0 FREQUENCY

6.1 N/A

7.0 EQUIPMENT & SUPPLIES

7.1 N/A

8.0 GENERAL INFORMATION

8.1 Every task or activity performed in accordance with GDP requirements, regulatory or Quality Systems shall be properly recorded and must comply with this procedure.

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8.2 All documentation generated in the course of business shall be permanent, legible and accurate. All entries must be made promptly, must be complete and must clearly represent the activities executed. All records must include sufficient detail to demonstrate compliance with the established procedures and allow an event, activity or process to be easily reconstructed at a later date.

8.3 The review process ensures that documentation is complete, free from misinterpretation, or error, and in compliance with this and any other applicable SOPs.

9.0 PROCEDURE

9.1 Recording Data

9.1.1 All documents must be filled out in indelible ink, blue or black only. Ink that can bleed or run when wet should not be used.

9.1.2 All entries should be recorded at the time the task is performed. **Back dating** (recording a prior date or time) **of entries is never permitted.**

9.1.3 All hand written entries must be signed or initialed and dated.

9.1.4 All steps must be completed in sequential order unless the procedure specifically allows for non-sequential completion.

9.1.5 Dates should be recorded following common U.S. practice of Month-Day-Year. The following are examples of acceptable formats of the date.

- 03/15/07
- 03/15/2007
- 03-15-07
- 3-15-07

9.1.6 Record times using the military format or using standard Hour: Minute format followed by AM/PM.

- For military format, use two digits indicating the hour from 00 to 23 followed by two digits indicating minutes from 00 to 59. Midnight is "0000". For example, 11:30 pm shall be noted as 2330.

9.1.6.1 If using standard format indicate the hour followed by a colon and then the minutes. Indicate AM or PM after the time.

9.1.7 For spaces that are not needed, line out the blank area with a single straight line and enter "N/A", date and initial the blank area.

9.1.8 The use of arrows, ditto marks ("), brackets and/or the word "same" is prohibited. Individual entries for each piece of data or entry, including initials and date, must be applied each time.

9.1.9 Personnel making entries or generating original data must sign the documentation in a manner that clearly identifies the person responsible for the activity and/or entry and when they made that entry or observation. This requirement also applies to anything entered in a "Comments" or "Notes" section.

9.1.10 If an entry was omitted and must be made at a time later than when the activity was performed, the documentation must clearly indicate the date performed and the date recorded. An explanation should be provided to substantiate the entry and the reason for the delay in recording.

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9.1.11 Quality records must be documented on official forms, notebooks or logs. Personal notebooks, legal pads, etc. must not be used.

9.1.12 In the unusual case where an employee must make an observation and an official document is unavailable, the paper record of the observation shall be initialed and dated and attached to the official document as soon as possible.

9.1.13 The data shall be transcribed to the official document and shall be notated "Transcribed, see attached original data record". The data shall be reviewed for accuracy as per routine review and approval of the official document.

9.1.14 For documentation of test results, the SOP, the test method or protocol that was followed must be evident from the record.

9.2 Units of measurement must be included on all documents. If not already specified on the form/attachment, the unit must be inserted after the value. The following units are most commonly used:

- °C (degrees Celsius)
- °F (degrees Fahrenheit)
- g/gm (grams)
- mg (milligrams)
- kg (kilograms)
- L (liter)
- mL (milliliter)

9.2.1 Recording Significant Figures

9.2.1.1 Record the number zero (0) before a decimal point if the value is less than one i.e. 0.257 rather than .257. Enter values to the full precision given by the data source unless otherwise specified in an applicable SOP, (e.g. if data source produces a result with 2 decimal places, 5.25, record the results as 5.25 rather than 5.3).

9.2.2 If one record must be attached to another (e.g. if a printout is to be attached to a lab notebook page), secure the attachment firmly with tape or staples. Assure that the attachment is initialed and dated and has sufficient identifying information to be traceable in the event it becomes separated.

9.3 Reviewing Data/Documentation

9.3.1 Documents should be promptly reviewed, usually within 30 calendar days unless a specific time frame is required by an established SOP or other requirement.

9.3.2 The reviewer cannot be the same as the person who performed the task. The only exception is when no other pharmacist is on duty to verify the formulation. In such a situation, the pharmacist must verify these circumstances on all applicable documents.

9.4 Correcting Errors

9.4.1 Correct entry by crossing out the entire incorrect entry with a single straight line. Write the correct data directly above or below the incorrect entry. The individual making the correction must initial/date the correction if there is not a

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same day date on the same page as the error. If there is a same day date on the page then just initials apply.

9.4.2 Any changes made to original data must be made in a manner that does not remove or obscure the original entry.

9.4.3 If the reason the correction is being made is not obvious, provide a brief explanation next to the correction.

9.4.3.1 If a correction is made to data that impacts the final result, a clear explanation must be given to detail the reason for the change.

9.4.4 Do not overwrite information to change a previously recorded entry.

9.4.5 Do not use any opaque substance, eraser, white tape, whiteout, or any other correction method that makes the original entry unreadable.

9.4.6 Corrections to errors are permitted by an individual other than the person who made the initial entry only if the error is obvious, if the information is retrievable from elsewhere or if the employee is no longer with the company. Supporting evidence or direct observation must have been made to support the correction and an explanation must be provided.

9.5 Voided Documents

9.5.1 Occasionally a document may be initiated and partially completed but is not required. In these cases the document cannot be discarded but must be voided.

9.5.2 If a document is to be voided, draw a diagonal line through the document and write "VOID."

9.5.3 Indicate the reason for voiding the document and initial/date the explanation.

9.5.4 Attach the voided document to the new document that replaces it. If no replacement exists, file with similar documents in chronological order or per routine filing convention. The voided document must be filed with or traceable to the document to which it relates.

9.6 Signatures

9.6.1 A signature consists of at least the first initial and full last name of the individual.

9.6.2 Initials may not be used when a document specifically requires a signature.

9.6.3 An employee is not permitted to sign another employee's name or initials.

9.6.4 An equivalently trained employee may sign on behalf of another employee using the format "John Doe for Frank Smith" followed by signature or initials and date of the individual making the entry.

9.6.5 All employees shall document their signatures and initials for traceability.

10.0 ATTACHMENTS

10.1 Attachment 1 – Signature Log

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11.0 HISTORY

Version Number	Date Effective	Description of Change	Change Request Number
1.0	03-08-06	New SOP	CR06037
2.0	11-21-07	Updates and minor changes, deleted attachment 1	CR07025
3.0	09-29-08	Added attachment 1/ Updated wording through-out document for clarity/ Updated responsibilities to reflect current roles	CR08020

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TITLE: GOOD DOCUMENTATION PRACTICES (GDP)

SOP NUMBER: 9.020 **VERSION NUMBER: 3.0**

SIGNATURE LOG- ATTACHMENT 1

Printed Name	Signature	Initials	Date

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TITLE: CORRECTIVE AND PREVENTATIVE ACTION (CAPA) MANAGEMENT	
SOP NUMBER: 9.030	**VERSION NUMBER: 2.0**
Non-Sterile and Sterile Laboratory	Effective Date 03-14-08
Originator:	
Reviewer:	

1.0 PURPOSE

1.1 The purpose of this procedure is to establish requirements for corrective and preventative action (CAPA).

2.0 SCOPE

2.1 This procedure applies to all compounding personnel at New England Compounding Center.

2.2 This procedure applies to all CAPAs that might result from analyzing processes, customer complaints, and audit reports.

2.3 The CAPA program is a management tool that summarizes corrective and preventative actions obtained from multiple operational sources. It is used to monitor for quality trends and take appropriate action as necessary.

3.0 RESPONSIBILTY

3.1 The Pharmacist-in-charge shall supervise this procedure and document that all personnel responsible for compounding will comply with this procedure.

4.0 REFERENCES

4.1 USP Current Version <797> "Pharmaceutical Compounding – Sterile Preparations"

4.2 SOP 1.030 "Deviations – OOS"

4.3 SOP 3.030 "Environmental Monitoring of the Clean Room Facility"

4.4 USP Current Version <795> "Pharmaceutical Compounding – Non-Sterile Preparations"

5.0 DEFINITIONS

5.1 CAPA – Corrective and Preventative Action

5.2 Corrective Action – Action taken to eliminate the cause of a detected nonconformity

5.3 Preventative Action – Action taken to prevent a nonconformity

5.4 OOS – Out of specification

6.0 FREQUENCY

6.1 When applicable

7.0 EQUIPMENT & SUPPLIES

7.1 N/A

8.0 GENERAL INFORMATION

8.1 The CAPA program involves:

- 8.1.1 Identifying problems that may require corrective action.
- 8.1.2 Deciding if corrective action is required.
- 8.1.3 Correcting the problem.
- 8.1.4 Investigating and determining the root cause(s) of the problem and proposing appropriate corrective action if necessary.

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8.1.5 Implementing the corrective action to eliminate the root cause(s).

8.1.6 Verifying that the corrective action is implemented and that it is effective.

9.0 PROCEDURE

9.1 Corrective Action

9.1.1 Any corrective action that is implemented in response to method deviations and/or modifications shall be documented in accordance with SOP 1.030, "Deviations – OOS."

9.1.2 Any corrective action that is implemented in response to an OOS result shall be documented in accordance with SOP 1.030, "Deviations – OOS."

9.1.3 Any corrective action that is implemented as a result of environmental monitoring excursions shall be documented in accordance with SOP 3.030, "Environmental Monitoring of the Clean Room Facility."

9.1.4 Any corrective action identified as a result of an internal or external audit or assessment.

9.1.5 Any corrective action identified as a result of a critical equipment failure (i.e. incubator, autoclaves, ovens, refrigerator/freezer, analytical balances, etc).

9.1.6 Any corrective action identified as a result of a customer complaint.

9.1.7 Any corrective action identified as a result of a product recall.

9.1.8 Whenever possible, determine the root cause(s) of the nonconformity.

9.1.9 Document the corrective action and the completion date on the appropriate form and evaluate the need for action to prevent recurrence of the nonconformance. Attach any supporting documentation to the form.

9.1.10 The Pharmacist-in-charge shall review and approve the corrective action and/or preventative action.

9.2 Preventative Action

9.2.1 Potential causes of nonconformities shall be evaluated in the process of quality planning and management review.

9.2.2 The need for preventative action shall be evaluated by the Pharmacist-in-charge to prevent occurrence of nonconformities and to determine the appropriate action.

9.2.3 Assign a sequential number to each CAPA. Document on the log. SOP 1.030 "Deviations-OOS" (Attachment 1). Review the CAPA log on a routine basis to assure that systemic issues are not occurring.

9.3 Not all corrective actions require a preventative action. If trending reports, service records, quality records, etc., indicate the need for preventative action, preventative action shall be taken before the trend develops into a critical issue.

9.4 CAPA Effectiveness Follow Up

9.4.1 The Pharmacist-in-charge and/or the compliance control officer shall be responsible for determining the effectiveness of CAPAs.

9.4.2 The completion date will be based on the complexity of the action required. If any extension of the due date is needed, there shall be documented rationale for the extension.

9.4.3 The Pharmacist-in-charge and/or the compliance control officer shall monitor CAPAs to assure timely execution and closure.

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10.0 ATTACHMENTS

10.1 N/A

11.0 HISTORY

Version Number	Date Effective	Description of Change	Change Request Number
1.0	03-08-06	New SOP	CR06038
2.0	03-14-08	Changed 9.3 to 9.2.3, added(Attachment 1)SOP 1.030	CR08010

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03-14-08

TITLE: FORMULA LOG SHEET – THE COMPOUNDER RX

SOP NUMBER: 9.040 **VERSION NUMBER: 2.0**

Non-Sterile and Sterile Laboratory Effective Date 05-10-12

Originator:

Reviewer: Barry J Cadden

1.0 PURPOSE

1.1 The purpose of this procedure is to establish requirements for the documentation and review of formulations used to compound preparations.

2.0 SCOPE

2.1 This procedure applies to all compounding personnel at New England Compounding Center.

3.0 RESPONSIBILITY

3.1 A pharmacist shall supervise this procedure and document that all personnel responsible for compounding will comply with this procedure.

4.0 REFERENCES

4.1 USP Current Version <795> "Pharmaceutical Compounding – Non-Sterile Preparations"

4.2 USP Current Version <797> "Pharmaceutical Compounding – Sterile Preparations"

4.3 USP Current Version <1075> "Good Compounding Practices"

4.4 SOP 9.020 "Good Documentation Practices (GDP)"

4.5 SOP 9.050 "Beyond-Use Dating (BUD) of Compounded Preparations"

4.6 SOP 9.110 "Sterile Compounding Finished Preparation Testing"

4.7 SOP 9.140 "Non-Sterile Compounding Finished Preparation Testing"

4.8 Appropriate reference texts and periodicals including, but not limited to:

- 4.8.1 Goodman and Gilman's: The Pharmacological Basis of Therapeutics
- 4.8.2 Martindale: The Extra Pharmacopoeia
- 4.8.3 Remington: The Science and Practice of Pharmacy
- 4.8.4 Rowe, Sheskey and Weller: The Handbook of Pharmaceutical Excipients
- 4.8.5 Trissel: Handbook on Injectable Drugs

4.9 "PCCA" Formulation Database

5.0 DEFINITIONS

5.1 Pharmacist – A qualified pharmacist with the authority to approve documentation and release each preparation.

5.2 FLS – Formula Log Sheet

6.0 FREQUENCY

6.1 The FLS shall be completed in "The Compounder Rx" before a compound is produced.

7.0 EQUIPMENT & SUPPLIES

~~7.1 Formula Log sheet (FLS)~~

7.2 Original or refill prescription order for the compounded preparation

7.3 "The Compounder Rx" software

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8.0 GENERAL INFORMATION

8.1 All compounded preparations can be made to a prescription or in anticipation of future prescription orders based upon clients regular prescribing habits. All prescription orders must be maintained on site for 5 years.

8.2 The FLS must be prepared and verified by a pharmacist before use in a compounded preparation.

8.3 The FLS shall list the following and is verified prior to release of the compounded product.

- 8.3.1 Product name and strength
- 8.3.2 Quantity
- 8.3.3 Date and time preparation was compounded
- 8.3.4 Lot Number
- 8.3.5 The assigned internal identification number and/or the prescription number
- 8.3.6 Dosage units
- 8.3.7 Assigned beyond-use date/ expiration date
- 8.3.8 The formulation record reference
- 8.3.9 The identification and quantity of ingredients
- 8.3.10 Instruction for compounding the formula
- 8.3.11 Batch yield
- 8.3.12 Sources and lot numbers/expiration dates of ingredients and devices
- 8.3.13 Initials of the person who prepared the compounded preparation
- 8.3.14 Initials of the pharmacist who verified the compounded preparation
    - 8.3.14.1 The reviewer cannot be the same person who performed the task. The only exception is when there is no other pharmacist on duty to verify the formula. This situation must be documented on the FLS.
- 8.3.15 Prepare sample testing for quality control, if applicable
- 8.3.16 Storage conditions
- 8.3.17 All in-process checks
- 8.3.18 All final product checks
- 8.3.19 Any other information pertinent in compounding the product

9.0 PROCEDURE

9.1 Most formulas are available in the software database

9.2 Upon receipt of a prescription, search the database for the product to be compounded

- 9.2.1 If a formula is not available and, one must be created follow directions at section 9.5.

9.3 To review a prescription, the following items shall be verified using a checkmark:

- 9.3.1 Patient's Name
- 9.3.2 Doctor's Name

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9.3.3 Drug name, strength, quantity and refills (if applicable)

9.3.4 Dosage instructions

9.3.5 Formula (verify that correct formula has been matched to the prescription order)

9.3.6 Due date and time

9.3.7 Any other information necessary for accurate fulfillment of the prescription order

9.3.8 Delivery information (if necessary)

9.4. The reviewer shall initial and date the prescription upon completion of review.

9.5. Creating a New Formula Log Sheet

9.5.1. A formula may only be written by the pharmacist in charge, or a designated staff pharmacist.

9.5.2. If the formula has been obtained from PCCA, record the formula as is, and reference the PCCA ID in the designated space.

9.5.3. If a formula is written in house, provide references as available to support the compounding activity and assigned beyond use date. If no published beyond-use date is available, assign a date according to SOP 9.050 "Beyond-Use Dating (BUD) of Compounded Preparations."

9.5.4. Provide step-by-step instructions for preparing the formula.

9.5.5. Print product labels/prescription labels (if applicable) and attach to the FLS.

9.5.6. For all new preparations, a qualified pharmacist must prepare the first formula and must have it verified by another pharmacist. The pharmacist may then make revisions to the formula as necessary. After the first formula is successful, proper training must be provided to all personnel that will be compounding this product.

9.5.6.1. Compounds with critical active ingredients may need additional testing to verify compounding quality. Refer to SOP 9.110, "Sterile Compounding Finished Preparation Testing" and/or SOP 9.10, "Non-Sterile Compounding Finished Preparation Testing."

9.6. Generating a Formula Log Sheet (existing formula)

9.6.1 Locate the formula and create a log entry and verify all the information required.

9.6.2 Print product labels/prescription labels (if applicable) and attach to the FLS.

9.6.3 After the verification is complete, the FLS, with labels, can be sent into the appropriate compounding suite.

9.6.4 The preparation is compounded in accordance with the instruction on the FLS.

9.6.5 As ingredients or components are added, the person (pharmacist or technician) places a checkmark on the FLS to indicate that that step has been completed.

9.6.5.1 Double-checking compounding accuracy as defined by a pharmacist and what is printed on the FLS must be followed during preparation and immediately prior to release.

9.7. Using a Formula Log Sheet in the compounding area.

~~9.7.1. Gather components and ingredients needed to formulate the preparation.~~

9.7.2. Double check the labels and confirm that the lot number and expiration date are correct. Initial the labels.

9.7.3. Weigh and/or measure all ingredients as described on the log sheet.

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9.7.4. Attach the printout of all weighed chemicals to the FLS. Document on the printout next to the weight, the name of the ingredient or chemical that the weight represents.

9.7.5. The FLS is kept with the compounded preparation throughout the compounding process.

9.7.6. Formulate the preparation as defined in the FLS. Indicate by use of a checkmark that the step has been completed. Each checkmark should be completed as the steps are completed. (Do not do all checkmarks at the end of the process).

9.7.7. If any manual calculations are done, the calculation should be written in long hand on the FLS.

9.8 At the end of the process, the formulated preparation is stored in quarantine until release of the preparation.

9.8.1 The FLS, the drug label and the prescription/order must all contain the same information.

9.8.2 A pharmacist must initial/sign and date the FLS.

9.8.3 The FLS shall be retained for five years as required for any prescription according to state law.

10 ATTACHMENTS

10.6 N/A

11. HISTORY

Version Number	Date Effective	Description of Change	Change Request Number
1.0	03-08-06	New SOP	CR06039
2.0	05-10-12	Needed to update	CR12005

TITLE: BEYOND-USE DATING (BUD) OF COMPOUNDED PREPARATIONS	
SOP NUMBER: 9.050	**VERSION NUMBER: 2.0**
Non-Sterile and Sterile Laboratory	Effective Date 02-19-08
Originator:	
Reviewer:	

1.0 PURPOSE

1.1 The purpose of this procedure is to establish requirements for determining a beyond-use date (BUD) for compounded preparations.

2.0 SCOPE

2.1 This procedure applies to all compounding personnel at New England Compounding Center.

3.0 RESPONSIBILITY

3.1 The Pharmacist-in-charge shall supervise this procedure and document that all personnel responsible for compounding will comply with this procedure.

4.0 REFERENCES

4.1 USP Current Version <795> "Pharmaceutical Compounding – Non-Sterile Preparations"

4.2 USP Current Version <797> "Pharmaceutical Compounding – Sterile Preparations"

4.3 USP Current Version <1150> "Pharmaceutical Stability"

5.0 DEFINITIONS

5.1 BUD – Beyond-use date

6.0 FREQUENCY

6.1 This procedure shall be performed for each compounded preparation.

7.0 EQUIPMENT & SUPPLIES

7.1 Appropriate reference materials

8.0 GENERAL INFORMATION

8.1 All compounded preparations must have an appropriate BUD.

9.0 PROCEDURE

9.1 BUDs shall be assigned based on current drug stability information and sterility considerations.

9.2 Consideration shall be given to all aspects of the finished product including drug reservoir, concentration and storage conditions.

9.3 A reliable method for determining BUDs shall be established, including laboratory testing of product stability, and chemical content when necessary.

- 9.3.1 Physical stability of the compounded preparation shall signify that the preparation has retained the original physical properties of the preparation, such as appearance, palatability, uniformity, dissolution and suspendability.
- 9.3.2 Chemical stability of the compounded preparation shall signify that each active ingredient has retained its chemical integrity and labeled potency within specified limits.

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9.3.3 Microbiological stability of the compounded preparation shall signify that sterility or resistance to microbial growth has been retained according to the specified requirements. Antimicrobial agents that are present shall retain their effectiveness within the specified limits.

9.3.4 Additional factors that affect the stability of the final preparation, and shall be considered, include pH, temperature, solvent, light, air, humidity, particle size, crystallization, vaporization and absorption.

9.4 In the absence of stability information that is applicable to a specific drug and preparation, the following maximum BUDs are recommended for compounded preparations packaged in tight, light-resistant containers and stored at controlled room temperature (unless otherwise indicated):

9.4.1 For non-aqueous liquids and solid formulations where the manufactured drug product is the source of the active ingredient, the BUD is no later than 25% of the time remaining until the product's expiration date or no later than six months (180 days), whichever is earlier.

9.4.2 For non-aqueous liquids and solid formulations where a USP or NF substance is the source of the active ingredient, the BUD is no later than six months.

9.4.3 For aqueous formulations prepared from ingredients in solid form, the BUD is no later than 14 days for liquid preparations when stored at 2°C-8°C.

9.4.4 For all other formulations, the BUD is no later than the intended duration of therapy or 30 days, whichever is earlier.

9.5 Applicable publications shall be referenced to obtain relevant stability, compatibility and degradation information regarding a drug or its congeners.

9.5.1 Referenced publications shall be available for compounding personnel. The reference library may include, but not be limited to, the following publications:

9.5.1.1 Facts and Comparisons

9.5.1.2 Handbook on Injectable Drugs, ASHP

9.5.1.3 Micromedex Electronic Drug Reference

9.5.1.4 Policies and procedures

9.5.1.5 Quality Control/Assurance documentation logs

9.5.1.6 United States Pharmacopeia

10.0 ATTACHMENTS

10.1 N/A

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11.0 HISTORY

Version Number	Date Effective	Description of Change	Change Request Number
1.0	03-08-06	New SOP	CR06040
2.0	02-19-08	Removed section 9.6, 9.7 and updated	CR08005

Remainder of this page intentionally left blank.

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TITLE: PRODUCT QUARANTINE, STORAGE, RELEASE AND DISPOSAL	
SOP NUMBER: 9.060	**VERSION NUMBER: 4.0**
Non-Sterile Laboratory	Effective Date 08-05-08
Originator:	
Reviewer:	

1.0 PURPOSE

1.1 The purpose of this procedure is to establish requirements for quarantine, storage, release and disposal of compounded products.

2.0 SCOPE

2.1 This procedure applies to all compounding personnel at New England Compounding Center.

2.2 This Procedure covers quarantine and disposal for all compounded medication for reasons of: expired, damaged, returned or other.

3.0 RESPONSIBILITY

3.1 The Pharmacist or Quality Control shall supervise this procedure and document that all personnel responsible for compounding shall comply with this procedure.

4.0 REFERENCES

4.1 USP Current Version <795> "Pharmaceutical Compounding – Non-Sterile Preparations"

4.2 USP Current Version <797> "Pharmaceutical Compounding – Sterile Preparations"

4.3 USP Current Version <1075> "Good Compounding Practices"

4.4 SOP 9.020 "Good Documentation Practices (GDP)"

4.5 SOP 9.070 "Recall of Compounded Product"

5.0 DEFINITIONS

5.1 MSDS – Material Safety Data Sheet

5.2 FIFO-First in First Out, in reference to expiration dates of products and materials

6.0 FREQUENCY

6.1 N/A

7.0 EQUIPMENT & SUPPLIES

7.1 N/A

8.0 GENERAL INFORMATION

8.1 Products to be dispensed and raw materials to be used in compounding should be organized in a manner that is in accordance with FIFO and allows the current lot to be visually identifiable.

9.0 PROCEDURE

9.1 Preparation Records

9.1.1 The Pharmacist shall maintain records of each preparation The following items shall be included:

9.1.1.1 The hard copy of the original prescription order

9.1.1.2 The formulation record

9.1.1.3 The compounding record, including all testing results and references to any investigations (if necessary)

9.1.1.4 Copies of all labeling

9.1.1.5 All disposal records of compounded products shall be retained for five years.

9.2 Storage

9.2.1 Each preparation shall be stored in strict accordance with the specific storage requirements for that preparation. This includes quarantined preparations that are awaiting release.

9.3 Release

9.3.1 The Pharmacist shall review the compounding record.

9.3.1.1 All records must comply with SOP 9.020, "Good Documentation Practices (GDP)."

9.3.1.2 Ensure the compounding record matches the original written order.

9.3.1.3 Make sure all calculations, weighing, measuring, order of mixing and compounding techniques were appropriate and accurately performed.

9.3.1.4 Check that storage conditions conform to specifications.

9.3.1.5 For sterile preparation, check that sterilization data conform to specifications.

9.3.1.6 Check that all finished preparation test results conform to specifications.

9.3.1.7 Visually inspect the finished preparation including the fill amount to ensure that it appears as expected. If the preparation is not distributed promptly, it must be again visually inspected just prior to leaving the storage area.

9.3.1.8 Visual inspection shall be performed for evidence of visible particulate or other foreign matter.

9.3.1.9 Visually inspect the container-closure integrity.

9.3.1.10 Examine all labeling to ensure the information matches the compounding and formulation record requirements.

9.3.1.11 A copy of all labeling should be attached to the formulation record.

9.3.1.12 If any discrepancies are observed, the preparation shall be immediately quarantined.

9.3.1.13 Sign and date the compounding record to affirm all procedures were carried out to ensure uniformity, identity, strength, quantity and purity.

9.4 Disposal of Raw Materials and Drug Product

9.4.1 In the event that raw material or drug product has expired, it shall be immediately placed in a carton or container marked "Non – Hazardous Waste."

9.4.1.1 Complete the disposal records (Attachments 1 through 4).

9.4.1.2 Raw material or drug product to be destroyed shall be disposed of by a legal, contracted firm.

9.4.2 In the case of disposing carcinogens, it shall be placed in a container marked " Hazardous Waste – Carcinogen"

9.4.2.1 Complete the disposal records (Attachment 5)

9.4.2.2 Raw material or drug product to be destroyed shall be disposed of by a legal, contracted firm.

10.0 ATTACHMENTS

10.1 Attachment 1 – Drug Disposal Log (CIII to CV)

10.2 Attachment 2 – Drug Disposal Log (CVI)

10.3 Attachment 3 – Expired Chemical Log (CIII to CV)

10.4 Attachment 4 – Expired Chemical Log (Inactive, CVI)

10.5 Attachment 5 – Carcinogen Drug Disposal Log

11.0 HISTORY

Version Number	Date Effective	Description of Change	Change Request Number
1.0	03-08-06	New SOP	CR06041
2.0	05-22-06	N/A	CR06056
3.0	02-28-08	Took out Attachments 1, 2, and 5 and section 9.2	CR08001
4.0	08-05-08	Minor changes and updates	CR08014

TITLE: PRODUCT QUARANTINE, STORAGE, RELEASE AND DISPOSAL	
SOP NUMBER: 9.060	VERSION NUMBER: 4.0

DRUG DISPOSAL LOG
(CIII to CV)

ATTACHMENT 1

Drug Name	Lot Number	Expiration Date	Number of Vials	Reason for Disposal**

**Use following codes for disposal:
D-damaged, **Extra,** **E**-expired, **F**-failed testing, **R**-returned, **X**-recalled

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TITLE: PRODUCT QUARANTINE, STORAGE, RELEASE AND DISPOSAL	
SOP NUMBER: 9.060	**VERSION NUMBER:** 4.0

DRUG DISPOSAL LOG
(CVI)

ATTACHMENT 2

Drug Name	Lot Number	Expiration Date	Number of Vials	Reason for Disposal**

**Use following codes for disposal:
D-damaged, **Extra**, **E**-expired, **F**-failed testing, **R**-returned, **X**-recalled

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EXPIRED CHEMICAL LOG
(CIII to CV)

ATTACHMENT 3

Drug Name	Lot Number	Expiration Date	Approximate Weight

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TITLE: PRODUCT QUARANTINE, STORAGE, RELEASE AND DISPOSAL
SOP NUMBER: 9.060 VERSION NUMBER: 4.0

EXPIRED CHEMICAL LOG (INACTIVE, CVI)

ATTACHMENT 4

Drug Name	Lot Number	Expiration Date	Approximate Weight

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CARCINOGEN DRUG LOG

ATTACHMENT 5

Drug Name	Lot Number	Expiration Date	Number of Vials	Reason for Disposal**

**Use following codes for disposal:
D-damaged, **Extra,** **E**-expired, **F**-failed testing, **R**-returned, **X**-recalled

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TITLE: RECALL OF COMPOUNDED PRODUCT	
SOP NUMBER: 9.070	**VERSION NUMBER: 1.0**
Non-Sterile and Sterile Laboratory	Effective Date 03-08-06
Originator:	
Reviewer: Barry J. Cadden	

1.0 PURPOSE

1.1 The purpose of this procedure is to establish requirements for recalling compounded products in the event a problem is encountered or suspected with the product.

2.0 SCOPE

2.1 This procedure applies to all compounding personnel at New England Compounding Center.

3.0 PERSONNEL

3.1 The Pharmacist-in-charge shall supervise this procedure and document that all compounding personnel will comply with this procedure.

4.0 REFERENCES

4.1 SOP 9.060 "Product Quarantine, Storage and Release"

5.0 DEFINITIONS

5.1 Consignee – Customer or patient that has received purchased or used the product subject to removal or correction.

5.2 Recall – Correction or removal of a distributed compounded product due to a known or suspected deficiency or nonconformance.

5.3 Removal – Physical removal of a compounded product from its point of use back to the pharmacy for destruction and/or inspection.

6.0 FREQUENCY

6.1 As needed

7.0 EQUIPMENT & SUPPLIES

7.1 Formulation compounding worksheet

7.2 Test results from third party laboratory (if applicable)

7.3 Product samples

7.4 In-house testing kits (if applicable)

7.5 Applicable records (lot numbers, facility name, patient names, etc.)

8.0 GENERAL INFORMATION

8.1 N/A

9.0 PROCEDURE

9.1 In the event that a compounded product is suspected or confirmed to have caused patient harm, was compounded incorrectly, or needs to be recalled for any other reason, all facilities and/or patients that received the product must be notified immediately.

9.2 A comprehensive list of all lot numbers affected shall be retrieved using all available data devices (formulation records, testing results, retained samples, hard copy files, etc.)

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9.3 The nature of the recall shall be explained by the Pharmacist-in-charge and a request will be made to check the affected lot numbers.

9.4 A formal recall letter shall be written, (Attachment 1) detailing the nature of the recall, affected lot numbers, and dates of dispensing to the facility and/or the patient.

9.5 The Pharmacist-in-charge shall ensure that all products that were dispensed are accounted for and/or that no harm was done to patients. The Pharmacist-in-charge shall complete the recall record.

9.6 New England Compounding Center will require all recalled product be returned to New England Compounding Center via prepaid delivery devices.

9.7 Upon receipt of recalled product, New England Compounding Center will quarantine the product for further analytical testing and evaluation of process malfunctions per SOP 9.060

9.8 Any deficiencies shall be addressed, problems shall be resolved and/or investigated, and a formal explanation of the outcome of the recall will be documented.

9.9 Any training and/or education required to prevent the process deficiencies from occurring in the future will be initiated immediately.

9.10 A copy of the investigation, the recall letter, quarantine records and destruction records shall be filed along with the recall records in a quality assurance file.

9.11 An effectiveness check must be documented to assure that all patients have been notified and that all affected product has been accounted for. Document the quantities on the Product Recall and Reconciliation report (Attachment 2).

9.12 The product must be dispositioned after closing the recall i.e. discard, rework etc.

    9.12.1 Document all destruction on the attachment in SOP 9.060

10.0 ATTACHMENTS

10.1 Attachment 1 – Recall Letter Template

10.2 Attachment 2 – Product Recall and Reconciliation

11.0 HISTORY

Version Number	Date Effective	Description of Change	Change Request Number
1.0	03-08-06	New SOP	CR06042

03-08-06

URGENT
PRODUCT RECALL

<Date>

<Customer Name>
<Address>
<City, State Zip>

Dear <Customer Name>,

Product Description:
Quantity:
Lot Number:
Date Dispensed

The above reference product is being recalled for <reason or nature of recall>. Please return all product to the address below utilizing the postage paid packaging enclosed. If you would like to report any adverse events, or if you would like to receive additional information regarding this product recall, please contact us at (800)944-6322 or (508) 820-0606 and request the Pharmacist-in-charge.

Regards,

<Pharmacist-in-charge>
New England Compounding Center
<Address>
<Phone>
<Fax>

03.08.06

PRODUCT RECALL AND RECONCILIATION

Complaint Number:____________________ **Date Recall Initiated:**______________

RECALLING PHARMACY

New England Compounding Center
697 Waverly Street, Framingham, MA 01702

Contact Person:__________________________

Preparation Name/Description	
Preparation Lot Number	
Reason for Recall	
Health Hazard Analysis	
Compounded Preparation Information **(Attach additional sheets as necessary)**	Date(s) Compounded:____________________ Date(s) Distributed:____________________ Total Volume Compounded:________________ Quantity Distributed:____________________ Qty. Remaining in Inventory:________________ Quantity Returned:____________________
Consignee List Attached? ☐ Y ☐ N	**Customer Notification Attached?** ☐ Y ☐ N

Completed By:______________________________ Date:______________

PRODUCT RECALL TERMINATION

Date Recall Closed:______________ Effectiveness Check Closed (Date):____________

Authorization for Termination of Recall

Pharmacist-in-Charge:__________________________ Date:______________

Quality Compliance Officer:______________________ Date:______________

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TITLE: OPERATION AND MAINTENANCE OF MERITECH CLEANTECH 2000S HAND WASHERS	
SOP NUMBER: 9.080	**VERSION NUMBER: 3.0**
Sterile Laboratory	Effective Date 12-22-08
Originator:	
Reviewer:	

1.0 PURPOSE

1.1 The purpose of this procedure is to outline the use and maintenance of the Meritech CleanTech 2000S automated hand washers.

2.0 SCOPE

2.1 This procedure applies to all sterile compounding personnel at New England Compounding Center using the Meritech CleanTech 2000S automated hand washers.

3.0 RESPONSIBILITY

3.1 The Pharmacist-in-charge shall supervise this procedure and document that all sterile compounding personnel will comply with this procedure.

4.0 REFERENCES

4.1 USP Current Version <797> "Pharmaceutical Compounding – Sterile Preparations"

4.2 SOP 1.060 "General Aseptic Technique"

4.3 SOP 3.020 "Cleaning and Maintenance of the Clean Room Facility"

4.4 SOP 9.090 "Required Garb for Clean Room Facility Access"

5.0 DEFINITIONS

5.1 N/A

6.0 FREQUENCY

6.1 This procedure shall be performed before entering the clean room facility.

6.2 Perform maintenance every 6 months as indicated in this procedure.

7.0 EQUIPMENT & SUPPLIES

7.1 Meritech CleanTech 2000S automated hand washer

7.2 Meritech Self-Clean Solution

7.3 Meritech Hand Cleansing Solution

7.4 Meritech Tubing Assembly

8.0 GENERAL INFORMATION

8.1 Before any operation in the clean room facility is started, personnel must thoroughly wash their hands with the Meritech CleanTech 2000S automated hand washer.

8.2 Proper hand washing by personnel will help protect product integrity and sterility.

9.0 PROCEDURE

9.1 The Compliance Monitor on the Front panel overlay as shown in Attachment 1 indicates the number of hand washes that have occurred. Attachment 2 shows front view of the Meritech Cleantech 2000S Hand washer unit.

9.2 There is a solution and self-clean monitor on the front panel overlay. Refer to Attachment 1.

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9.2.2 If the needle is in the "empty" region, this indicates lower than normal flow due to empty solution containers or mechanical problems. Check solutions and replace/repair as necessary.

9.2.3 If the needle is in the "blockage" region, this indicates a mechanical problem. Troubleshoot as necessary.

9.3 During extended periods of inactivity, i.e. plant shut down, remove solution containers and place each tubing line in containers of hot water.

9.3.1 Run the system through 6 self-clean cycles and 12 hand washes to purge the lines.

9.3.2 Unplug the system.

10.0 Operation

10.1 Operation instructions also appear in SOP 9.090.

10.1.1 Stand directly in front of Hand Washing Unit.

10.1.2 Confirm the Compliance Monitor is illuminated.

10.1.3 Place hands simultaneously into the center of each cylinder. The cycle will begin automatically as hands enter.

10.1.4 Spread fingers and position hands at a depth so that the outer most ring of the water spray covers the wrist.

10.1.5 Allow hands to remain in the cylinders until the turning has stopped to indicate cycle is complete.

Note: *Do not rest hands or arms on sides of cylinders.*

10.1.6 Remove hands and dry with low-lint wipes.

Note: *The optical sensor will not reset until hands are removed.*

10.1 Hand Wash Cycle

10.1.1 During each wash cycle 3-5ml of antimicrobial solution is aspirated and delivered to the hands through the jet nozzles.

10.1.2 The cycle consists of a wash with antimicrobial solution followed by a potable water rinse.

10.2 Self-Clean Cycle

10.2.1 A self-clean cycle will automatically occur every 24 hours or when the unit is re-started.

10.2.2 A hard surface disinfectant is dispensed and then rinsed out of the system.

10.2.3 If hands are inserted during a self-clean cycle, the unit will automatically switch to a hand wash cycle. Once hands are removed the self-clean will re-start.

10.3 Maintenance

10.3.1 Clean exterior of unit as needed.

10.3.2 Change solutions as needed.

10.4 Changing Solution Containers

10.4.1.1 Remove the empty container by disconnecting the tubing from the horizontal connection at the top of the bottle.

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10.4.1.1 Remove the empty container by disconnecting the tubing from the horizontal connection at the top of the bottle.

10.4.1.2 Unscrew the protective cap from the new solution container and discard.

10.4.1.3 Remove the tube assembly that was provided with the new solution container from the plastic bag.

10.4.1.4 Insert the new tube assembly in the new solution container and tighten bottle cap.

10.4.1.5 Install new container into the appropriate location in the bottom of the unit.

10.4.1.6 Slip the end of the tubing onto the connector on the cap of the new solution container.

10.4.1.7 After installing hand cleansing solution, trigger a wash cycle and allow the system to prime the solution.

10.4.1.8 After installing self-clean solution, turn off the unit, wait 3 seconds, and turn back on to trigger a self-clean cycle.

10.5 Biannual Maintenance

10.5.1 Preventative maintenance done by a Meritech Service Engineer 1-800-932-7707

11.0 ATTACHMENTS

11.1 Attachment 1 - View of overlay for Meritech CleanTech 2000S Hand Washer

11.2 Attachment 2 - Front View of Meritech CleanTech 2000S Hand Washer

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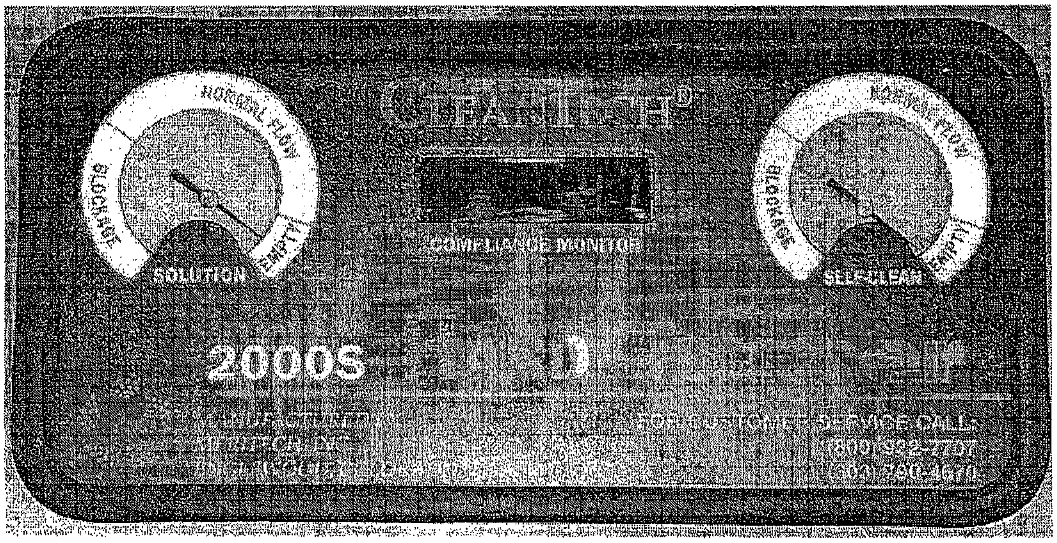
ATTACHMENT 1 – VIEW OF OVERLAY FOR MERITECH CLEANTECH 2000S HAND WASHER

CleanTech® 2000S



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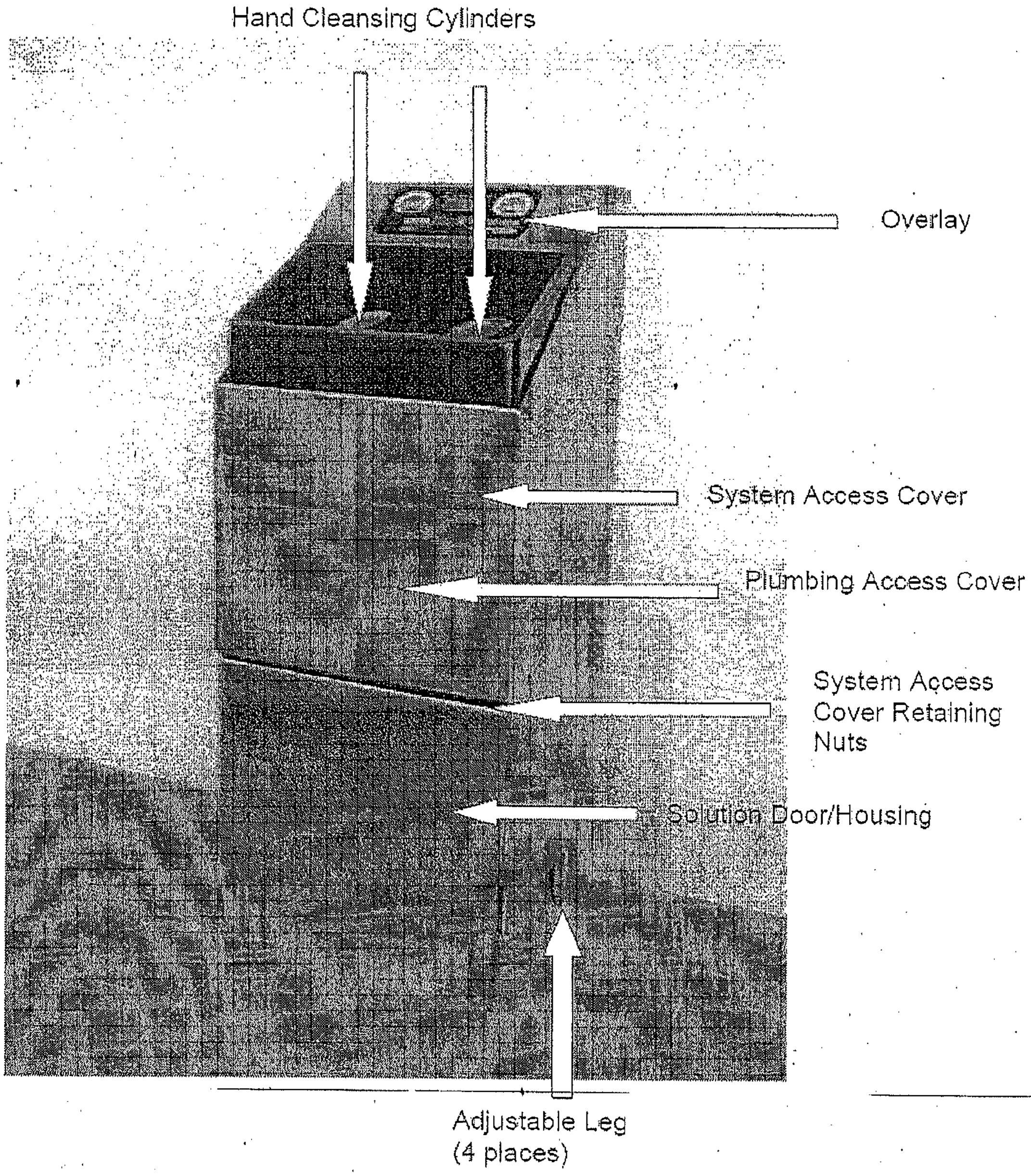
ATTACHMENT 2 – FRONT VIEW OF MERITECH CLEANTECH 2000S HAND WASHER

2000S Layout

Layout, Front View



11.3 HISTORY

Version Number	Date Effective	Description of Change	Change Request Number
1.0	03-08-06	New SOP	CR06043
2.0	12-21-07	Minor changes and updates	CR07027
3.0	12-22-08	Changed to an Automatic Hand Washer	CR08021

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TITLE:	**REQUIRED GARB FOR CLEAN ROOM FACILITY ACCESS**		
SOP NUMBER:	**9.090**	**VERSION NUMBER:**	**4.0**
Sterile Laboratory		Effective Date	12-22-08
Originator:			
Reviewer:			

1.0 PURPOSE

1.1 The purpose of this procedure is to establish gowning requirements for entering the clean room facility.

2.0 SCOPE

2.1 This procedure applies to all sterile compounding personnel at New England Compounding Center.

3.0 RESPONSIBILITY

3.1 The Pharmacist-in-charge shall supervise this procedure and document that all personnel working or entering the clean room facility will comply with this procedure.

4.0 REFERENCES

4.1 USP Current Version <797> "Pharmaceutical Compounding – Sterile Preparations"

4.2 SOP 1.060 "General Aseptic Technique"

4.3 SOP 3.020 "Cleaning and Maintenance of the Clean Room Facility"

4.4 SOP 9.080 "Operation and Maintenance of Meritech CleanTech 2000S"

5.0 DEFINITIONS

5.1 N/A

6.0 FREQUENCY

6.1 This procedure shall be performed when entering the clean room facility.

7.0 EQUIPMENT & SUPPLIES

7.1 Non-shedding garb
- 7.1.1 Sterilized Coveralls/Frock/Disposable gown
- 7.1.2 Bouffant
- 7.1.3 Beard covers (if applicable)
- 7.1.4 Face mask
- 7.1.5 Booties
- 7.1.6 Disposable gloves
- 7.1.7 Sterile 70% Isopropyl Alcohol (IPA)
- 7.1.8 Eye protection (as needed)
- 7.1.9 Sporicidin
- 7.1.10 2% Bleach
- 7.1.11 Spor-Klenz®
- 7.1.12 Vesphene
- 7.1.13 LpH
- 7.1.14 Low lint wipes

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GENERAL INFORMATION

8.0 Sterile compounding personnel must be properly gowned to protect product integrity and sterility. Sterile70% IPA frequently.

8.1 Gloves shall be disinfected with sterile 70% IPA frequently when working in clean room areas.

8.2 Disposable gowns must have long sleeves with elastic bands, and be at least knee-length.

8.3 Booties must fit completely over shoes and shoelaces.

8.4 When gowning, use minimal manipulations to reduce microbial contamination.

8.5 Materials that shed particle, such as cardboard or wood products, shall not enter the clean room facility..

8.6 Disposable gowning materials shall be discarded after each use when leaving the clean room areas.

8.7 Personnel who have a potentially contagious disease or who have open wounds/lacerations should immediately contact the pharmacist in charge before proceeding.

8.8 Coveralls/Frocks/Disposable gowns shall be stored for re-use on designated hooks. Face mask and bouffant are to be disposed of, upon exit.

8.9 Personnel are required to put on new gowning materials each day and whenever they become visibly soiled.

8.10 De-gowning procedures do not need to be followed in the event of an emergency evacuation.

9.0 PROCEDURE

9.1 Personnel must remove all makeup and jewelry from face, hands, and arms prior to entering the clean room facility.

9.2 Step on tacky mat out side gown room.

9.3 Open door to gown room and step on tacky mat inside the gown room.

9.4 Put on a bouffant. Make sure that hair is completely covered.

9.5 Put on a beard cover (if appropriate) and ensure that hair is completely covered.

9.6 Put on a face mask.

9.7 While standing on the tacky mat, place a bootie on one foot. Move the covered foot onto the clean side of floor.

9.8 Place a bootie on the other foot and step onto clean side. **(At no time shall a non-covered shoe touch the floor of the clean side or a covered shoe touch the tacky mat).**

9.9 Clean hands thoroughly with the **Automatic Hand Washer**.

9.9.1 Stand directly in front of hand washing unit.

9.9.2 Confirm the compliance monitor is illuminated.

9.9.3 Place hands simultaneously into the center of each cylinder. The cycle will begin automatically as hands enter.

9.9.4 Spread fingers slightly and position hands at a depth so that the outer most ring of the water spray covers the wrist.

AMK 12-22-08

9.9.5 Allow hands to remain in the cylinders until the turning has stopped (to indicate cycle is complete).
NOTE: Do not rest hands or arms on sides of cylinders.

9.9.6 Remove hands and dry hands with low-lint wipes.

9.10 Obtain a clean coverall/frock/disposable gown. Ensure that coverall/frock/disposable gown is not damaged. Do not use damaged gowning materials.

9.10.1 Personnel should take care to prevent coverall/frock/disposable gown from touching the floor.

9.10.2 Put on coverall/frock and zipper/snap up completely and adjust the collar so that the coverall/frock fits snugly around the neck.

9.10.3 Close the snaps at the bottom of the coveralls to prevent the suit from dragging on the floor.

9.10.4 Disposable gown must have long sleeves with elastic wristbands and should be at least knee-length.

9.10.5 The disposable gown should fit snugly around the neck. Thumbs should be put through a hole in the end of each sleeve, to prevent sleeve from sliding up arm.

9.10.6 Make sure no loose clothing is exposed, such as shirt collars, hoods or sleeves.

9.11 Put on a pair of clean gloves

9.11.1 Remove a glove from the glove dispenser or bag, touching only the wrist part of the glove. **Do not touch the fingers of the gloves.**

9.11.2 Place the entire hand inside the glove and pull the collar of the glove up to the wrist and over the elastic wristband of the coverall/frock/disposable gown. **Do not place wrist of coverall/frock/disposable gown over gloves.**

9.11.3 Repeat above steps for the second glove.

9.11.4 Spray gloves with sterile 70% IPA and allow to dry before entering the clean room.

9.11.5 If gloves are torn or punctured, remove and discard the contaminated glove, and put on a clean pair following the steps above.

9.11.6 If personnel exit the clean room areas for any reason, de-gown per 9.12 and repeat the gowning process upon re-entry.

9.12 De-gowning

9.12.1 When ready to leave the gown room, remove coverall/frock/disposable gown and take care not to touch the coverall/frock/disposable gown to the floor when removing. Hang coverall/frock//disposable gown on designated hook and exit the gown room.
NOTE: If the coverall/frock/disposable gown is not visibly soiled or damaged it may be re-used for the remainder of the day.

9.12.2 If the coverall/frock/disposable gown will not be re-used for the remainder of the day, exit gown room to remove all gowning materials.

9.12.3 If soiled or when done in clean room, remove coverall/frock/disposable gown and place in soiled garment container.

9.12.4 Remove bouffant and face mask after exiting the gown room. **Dispose of immediately. Do not wear these materials in other areas of the facility.**

10.0 ATTACHMENTS

10.1 Attachment 1 - Gowning Process

11.0 HISTORY

Version Number	Date Effective	Description of Change	Change Request Number
1.0	03-08-06	New SOP	CR06044
2.0	03-30-06	Added section 9.4.4.	CR06058
3.0	12-22-08	Minor updates and changes	CR07020

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12-22-08

GOWNING PROCESS

(OUTSIDE THE GOWN ROOM)

TACKY MAT

↓

(INSIDE THE GOWN ROOM)

TACKY MAT

↓

BOUFFANT/BEARD COVER

↓

FACE MASK

↓

BOOTIES

↓

AUTOMATED HAND WASHER

↓

COVERALL/FROCK/DISPOSABLE GOWN

↓

GLOVES

↓

SPRAY GLOVES WITH STERILE 70% ISOPROPYL ALCOHOL (IPA)

↓

ENTER CLEAN ROOM - ISO 6 (CLASS 1,000)

ORIGINAL
12-22-08

③

TITLE: STERILE COMPOUNDING PROCESS VALIDATION (MEDIA FILLS)	
SOP NUMBER: 9.100	**VERSION NUMBER: 2.0**
Sterile Laboratory	First effective Date: 02-08-06
Originator:	Previous Effective Date: 03-08-06
Reviewer:	Current Effective Date: 02-28-08

PURPOSE

1.1 The purpose of this procedure is to establish requirements for sterile compounding process validations (media fills) in accordance with USP <797>.

2.0 SCOPE

2.1 This procedure applies to all sterile compounding personnel at New England Compounding Center.

3.0 RESPONSIBILITY

3.1 The Pharmacist-in-charge shall supervise this procedure and document that all sterile compounding personnel will comply with this procedure.

4.0 REFERENCES

4.1 USP Current Version <797> "Pharmaceutical Compounding – Sterile Preparations"

4.2 SOP 2.030 "Sterile Compounding Personnel Qualification"

4.3 SOP 3.020 "Cleaning and Maintenance of the Clean Room Facility"

4.4 SOP 3.030 "Environmental Monitoring of the Clean Room Facility"

5.0 DEFINITIONS

5.1 Aseptic Filling – process in which a pre-sterilized product is transferred to a sterile container(s)

5.2 Aseptic Processing – the aseptic filling of product containers and/or devices in a controlled environment where the air supply, materials, equipment and personnel are regulated to control microbial and particulate contamination to acceptable levels

5.3 Aseptic Processing Area – controlled environment for sterile compounding; consists of several zones in which the air supply, materials, equipment and personnel are regulated to control microbial and particulate contamination to acceptable levels

5.4 Critical Processing Zone – region of aseptic processing area in which product and contact surfaces are exposed to the environment

5.5 Media Fill – method of evaluating an aseptic process using a microbial growth medium

5.6 CSP – Compounded Sterile Preparation

6.0 FREQUENCY

6.1 High-Risk Level – each person at least semi-annually

7.0 EQUIPMENT & SUPPLIES

7.1 ISO Class 4 (Class 10) microenvironment

7.2 See" Compounder " for Media Fill (Personal) 3% Injection

7.3 Each aseptic employee must perform 3 consecutive media fills runs without evidence of turbidity< (-) control> prior to working with sterile medications/formulations.

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02-15-08

7.4 3GMS Soybean-Casein Digest Medium Powder

7.5 100 ML Sterile water for injection

7.6 Sterile weigh-cup

7.7 (3) 35 ML LL Sterile syringes

7.8 (18) Sterile 10mL clear vials (1) for Control, (5) for sterile

7.9 (3) 0.22M Disk filters

7.10 (3) 18G LL needles

7.11 (3) Red LL syringe caps

7.12 Flip-Top Caps

7.13 (18) 20MM stoppers...3 for Controls are **non sterile**

7.14 Sterile 70% isopropyl alcohol (IPA) or disinfectant in use

7.15 Sterile Rubber Closures

7.16 Incubator

7.17 (4) TSA contact plates

8.0 GENERAL INFORMATION

8.1 Media fills must be conducted without interruption.

8.2 Media fills shall be performed under the most challenging or stressful conditions encountered during compounding.

9.0 PROCEDURE

9.1 Media Fill Procedures

9.1.1 Verification of growth promotion of media may be done concurrently with the media fill and verified after the media fill run (certificate of analysis indicating vendor Growth Promotion is acceptable).

9.1.1.1 The incubation temperature will be the same as that used for the media filled units.

9.1.1.2 The medium selected must be capable of growing a wide spectrum of microorganisms and of supporting microbiological recovery and growth of low numbers of microorganisms.

9.1.2 High-Risk Media Fills

9.1.2.1 All media fills shall be conducted using the current compounder records.

9.1.2.2 All critical steps must occur in an ISO Class 4 (Class 10) microenvironment.

9.1.2.3 Disinfect the glove box in accordance with SOP 3.020, "Cleaning and Maintenance of the Clean Room Facility."

9.1.2.4 Components should be assembled and brought into the sterile area in a clean tote or equivalent.

9.1.2.5 Disinfect each component prior to placing in the glove box.

9.1.2.6 Weigh using an electronic analytical balance, 3g of Soybean-Casein Digest Medium in a sterile weigh cup to make a 3% solution. Print weight and attach to log sheet.

9.1.2.7 Add 80% of final volume of sterile water for injection to sterile cup. Add spin bar and cover.

9.1.2.8 Spin until completely dissolved. QS to final volume.

9.1.2.9 Draw 30mL of above solution into (3) separate 35ML lure lock syringes via 18 gauge needle then cap syringes.

9.1.2.10 Outside class-10 hood transfer 5mL of the solution from each syringe into separate sterile 10mL clear vials.

9.1.2.11 The above 3 vials are to be treated and labeled as **controls** they generate exponential microbial growth, indicated by visible turbidity upon incubation.

9.1.2.12 Using proper aseptic technique transfer the 3 syringes and all other necessary materials containing 25ML of 3% soybean solution into the class-10 microenvironment.

9.1.2.13 Attach a sterile 0.2M disk and an 18 gauge needle to each syringe and filter 5ML of the 3%TSB solution into each of the (5) x 10ML clear vials...Repeat process for each syringe.

9.1.2.14 Cap, crimp and label each vial.

9.1.2.15 Incubate vials for 14 days at 25-35 °C and check for turbidity at 14 days.

9.2 Incubation and Inspection of Media-Filled Units

9.2.1 Leaking or damaged media fill units must be removed, and documented why the reason for removal.

9.2.2 All media fill units shall be incubated for 14 days at 25-35°C.

9.2.3 All media fill units shall be stored or manipulated to allow contact of the media with all product contact surfaces in the unit.

9.2.4 At the end of 3, 7 and 14 day incubation period, each media fill unit shall be visually inspected for the presence of microbial growth.

9.2.5 Media must be transferred into a clear glass container if the container is not suitable for visual inspection.

9.3 Contamination with Media

9.3.1 Contamination of the area and equipment with media during media-fill runs shall not compromise the quality of the facility and equipment or the product subsequently processed using the same facility and equipment.

9.3.2 Media spills must be handled properly and promptly by cleaning, disinfecting and, if necessary, sterilizing the facility and equipment.

9.4 Documentation Requirements for Media Fills

9.4.1 The Validation of Personnel – Sterile Compounding form (Attachment 2 of SOP 2.030, "Sterile Compounding Personnel Qualification") shall include, but not be limited to, the following items:

9.4.1.1 Date and location of media fill

9.4.1.2 Container/closure descriptions (type, lot number and size)

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9.4.1.3 Volume filled

9.4.1.4 Filter brand/description and lot numbers/expiration date (if applicable)

9.4.1.5 Type of media used, lot number/expiration date and growth promotion date/results (if purchased, a certificate of growth promotion should be maintained on file)d

9.4.1.6 Number of units rejected at inspection and reason for rejection

9.4.1.7 Number of units incubated and incubation time/temperature

9.4.1.8 Number of positive units at the conclusion of the incubation

9.4.1.9 Results (pass/fail)

9.4.2 Touch Plates

9.4.2.1.1 The compounder shall take two samples of his or her dominant hand to monitor aseptic technique. **Prior to disinfecting gloves**, the compounder shall touch each gloved fingertip to the agar surface, making certain to not re-touch areas.

9.4.2.1.2 Gloves must be disinfected prior to continuing the media fill after touching the agar surface.

9.4.2.2 Disinfect each sampled surface immediately after the sample is taken with sterile 70% IPA.

9.4.2.3 There shall be one positive control contact plate for each lot of media used. Touch the agar surface with an un-gloved fingertip, replace the lid, label the plate appropriately and incubate according to step 9.2.2.

9.4.2.4 There shall be one negative control contact plate for each lot of media used. Label an unopened plate appropriately and incubate according to step 9.2.2.

9.4.3 Incubation of Environmental Controls and Samples

9.4.3.1 All plates shall be incubated at 20 - 25°C for three days and then incubated at 30-35°C for three days.

9.4.3.2 Plates should be checked daily for growth.

9.5 Acceptance Criteria

9.5.1 All media must demonstrate growth promotion capabilities

9.5.1.1 If no growth is observed in the growth promoting containers, repeat the growth promotion study with new components. Incubate the samples at 30-35°C with a negative control for seven days or until growth is observed. If no growth is observed, the medium is unacceptable for use, and the results of the media fill are invalid.

9.5.1.2 A Certificate of Analysis indicating vendor growth promotion is acceptable.

9.5.2 Calibration documentation of all equipment must be current and verified.

9.5.3 The clean room temperature must be maintained at 60°F – 70°F.

9.5.4 The clean room humidity must be maintained in the 15% – 60%.

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10.0 ATTACHMENTS

N/A

11.0 HISTORY

Version Number	Date Effective	Description of Change	Change Request Number
1.0	03-08-06	New SOP	CR06045
2.0	02-28-08	Took out attachment 1, section 9.1.2, 9.1.3, 9.5 changes to sections 9.5.2.2, 9.5.3, 9.6 and other changes and updates.	CR08004

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02-18-08

(9)

TITLE: STERILE COMPOUNDING FINISHED PREPARATION TESTING	
SOP NUMBER: 9.110	**VERSION NUMBER: 2.0**
Sterile Laboratory	First Effective Date 02-08-06
Originator:	Previous Effective Date 03-08-06
Reviewer:	Current Effective Date 02-28-08

1.0 PURPOSE

1.1 The purpose of this procedure is to establish requirements and documentation for finished preparation testing of sterile compounded preparations.

2.0 SCOPE

2.1 This procedure applies to all sterile compounding personnel at New England Compounding Center.

3.0 RESPONSIBILITY

3.1 The Pharmacist-in-charge shall supervise this procedure and document that all sterile compounding personnel responsible for finished preparation testing comply with this procedure.

3.2 It is the responsibility of New England Compounding Center to review and assess the contract laboratory for appropriate regulatory compliance.

4.0 REFERENCES

4.1 USP Current Version <797> "Pharmaceutical Compounding – Sterile Preparations"

4.2 USP Current Version <71> "Sterility Testing"

4.3 USP Current Version <85> "Bacterial Endotoxin Testing"

4.4 USP Current Version <1075> "Good Compounding Practices"

4.5 All Mass State Board requirements

4.6 SOP 6.020 "Product Labeling"

4.7 SOP 9.050 "Beyond-Use Dating (BUD) of Compounded Preparations"

4.8 SOP 9.060 "Product Quarantine, Storage and Release"

4.9 SOP 9.070 "Recall of Compounded Product"

5.0 DEFINITIONS

5.1 CSP – Compounded Sterile Preparation

6.0 FREQUENCY

6.1 Testing requirements are dependent on USP monographs for each compound. It is the responsibility of New England Compounding Center to determine which tests can be performed in-house and which tests must be performed at a contract facility.

7.0 EQUIPMENT & SUPPLIES

7.1 Third party analytical testing laboratory (if applicable)

ORIGINAL 02-28-08

7.2 Lint-free wipes

7.3 Powder-free latex or nitrile gloves

8.0 GENERAL INFORMATION

8.1 This procedure is designed for planned testing to verify and demonstrate effectiveness of all procedures critical to the accuracy and purity of the finished compounded product.

8.2 All compounded sterile products must be tested according to USP <797> and other referenced chapters and monographs.

8.2.1 USP <71> must be followed when a sterility test is required. Within chapter <71>, the number of units, volume per unit and specific methods are discussed.

8.2.2 USP <71> states, "The following culture media have been found to be suitable for the test for sterility. Fluid Thioglycollate Medium is primarily intended for the culture of anaerobic bacteria. However, it will also detect aerobic bacteria. Soybean-Casein Digest Medium is suitable for the culture of both fungi and aerobic bacteria."

9.0 PROCEDURE

9.1 Sterility Testing

9.1.1 Low-risk level preparations shall be tested for sterility:

9.1.1.1 Before administration.

9.1.1.2 If stored at room temperature for more than 48 hours.

9.1.1.3 If stored at 2°C - 8°C for more than 14 days.

9.1.1.4 If stored at frozen conditions (less than -20°C) for more than 45 days.

9.1.2 Medium-risk level preparations shall be tested for sterility:

9.1.2.1 Before administration.

9.1.2.2 If stored at room temperature for more that 30 hours.

9.1.2.3 If stored at 2°C - 8°C for more than 7 days.

9.1.2.4 If stored at frozen conditions (less than -20°C) for more than 45 days.

9.1.3 High-risk level preparations shall be tested for sterility:

9.1.3.1 Before administration.

9.1.3.2 If stored at room temperature for more than 24 hours.

9.1.3.3 If stored at 2°C - 8°C for more than 3 days.

9.1.3.4 If stored at frozen conditions (less than -20°C) for more than 45 days.

9.1.3.5 If drug(s) that will be injected into vascular and/or central nervous systems is/are prepared in groups of more than 25 identical, individual single-dose packages, or in multiple dose vials for administration to multiple patients.

9.1.3.6 If, prior to sterilization, drug(s) that will be injected into vascular and/or central nervous systems is/are stored at 2°C - 8°C for more than 12 hours or stored at temperatures above 8°C for more than 6 hours.

9.1.4 Sterility sampling requirements must follow the tables in USP <71>, "Sterility Testing."

9.1.5 Sterility methods must follow the USP <71> membrane filtration method (if applicable). If not performing membrane filtration, other methods outlined in USP <71> are acceptable.

9.1.6 If a rapid sterility test is used, it must be proven that the method is as effective and as reliable as the USP method(s).

9.2 Endotoxin (Pyrogen) Testing

9.2.1 High-risk level preparations:

9.2.1.1 CSPs for administration via injection into the vascular and central nervous systems that are prepared in groups of more than 25 identical individual single-dose packages, or in multiple dose vials for administration to multiple patients, must not contain excessive bacterial endotoxins.

9.2.1.2 CSPs that are exposed to 2°C - 8°C for more than 12 hours or that are exposed to temperatures above 8°C for more than 6 hours before sterilization must be tested for excessive endotoxins.

9.2.2 The endotoxin testing shall follow the USP <85> bacterial endotoxin test method(s).

9.2.3 In the absence of a bacterial endotoxin limit in the official monograph or other CSP formula source, the CSP must not exceed the amount of USP Endotoxin Units (EU per hour per kg of body weight or m^2 of body surface area) specified in USP <85> for the appropriate route of administration.

9.2.4 One unit per batch must be sampled.

9.3 Physical Testing Requirements

9.3.1 The end product must be visually inspected for:

9.3.1.1 Container leaks

9.3.1.2 Integrity

9.3.1.3 Solution cloudiness or phase separation

9.3.1.4 Appropriate color

9.3.1.5 Appropriate volume

9.3.2 Particulate testing (liquids)

9.3.2.1 Sampling (one unit per batch and, if placed in storage, immediately before shipping).

9.3.2.2 Wipe the container with a damp, lint-free wipe to remove any external particles.

9.3.2.3 Using powder-free gloves, hold the container by its top and swirl the contents by rotating the wrist in a circular motion.

9.3.2.4 Hold the container horizontally about four inches below a light source against a white and/or black background and move the container back and forth.

9.3.2.5 Slowly invert the container and look for heavy particles that may have settled on the bottom of the container.

9.4 Accuracy Requirements

9.4.1 Accuracy must meet Mass State Board requirements.

9.4.2 All calculations and volumes must be verified on the formulation sheet (e.g. if the total volume shall be 5mL, then fill 5mL of water into a container of similar size/shape and visually compare).

9.5 Identification and Potency Requirements

9.5.1 Verify the label has the correct:

9.5.1.1 Names

9.5.1.2 Amounts or concentrations of ingredients

9.5.1.3 Total volume

9.5.1.4 Beyond-use date

9.5.1.5 Appropriate route(s) of administration

9.5.1.6 Storage conditions

9.5.1.7 Other safe use information as needed

9.5.2 Verify the compounding record to the original written order for correct identities of ingredients, purity of ingredients and amounts of ingredients. If any of these cannot be confirmed accurate, the preparation must be assayed by methods that are specific for the active ingredients based on USP monographs

9.5.3 Verify that correct fill volumes and quantities of units were prepared.

9.5.4 At the discretion of the Pharmacist-in-charge, samples shall be tested for potency using the appropriate method or samples shall be sent to a contract lab for testing. Samples that are awaiting potency results must be quarantined as per SOP 9.060, "Product Quarantine, Storage and Release."

9.6 If any of the finished product testing is out of specification, an investigation must be performed to determine if a product recall (SOP 9.070) is necessary.

10.0 ATTACHMENTS

10.1 Attachment 1 – Test Results Data Sheet (Sterile)

11.0 HISTORY

Version Number	Date Effective	Description of Change	Change Request Number
1.0	03-08-06	New SOP	CR06046
2.0	02-28-08	Removed sections 9.4.3, 9.6 and 9.7	CR08006

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02-28-08

TEST RESULTS DATA SHEET (STERILE)

Product Name: ______________________________ **Lot #:** ____________________

Prepared By: ______________________________ **Date:** ____________________

Pharmacy testing results acceptable? ☐Yes ☐No ☐N/A

If "No," OOS/Investigation number: ______________________________

Copy of final investigation results attached? ☐Yes ☐No (explain)

____

____

____

____

If "N/A," contract laboratory results acceptable? ☐Yes ☐No

Contract laboratory investigation results attached? ☐Yes ☐No (explain)

____

____

____

____

Contract laboratory final results attached? ☐Yes ☐No (explain)

____

____

____

____

Completed By: ______________________________ **Date:** ____________________
Pharmacist-in-charge

ORIGINAL
08-25-08

TITLE: REQUIRED GARB FOR NON-STERILE COMPOUNDING AREA	
SOP NUMBER: 9.120	**VERSION NUMBER: 2.0**
Non-Sterile Laboratory	Effective Date 07/26/07
Originator:	
Reviewer:	

1.0 PURPOSE

1.1 The purpose of this procedure is to establish gowning requirements for entering the non-sterile compounding area.

2.0 SCOPE

2.1 This procedure applies to all non-sterile compounding personnel at New England Compounding Center.

3.0 RESPONSIBILITY

3.1 The Pharmacist-in-charge shall supervise this procedure and document that all personnel working or entering the non-sterile compounding area will comply with this procedure.

4.0 REFERENCES

4.1 USP Current Version <795>, "Pharmaceutical Compounding – Non-Sterile Preparations"

4.2 SOP 1.050 "General Non-Sterile Compounding Technique"

4.3 SOP 3.050 "Cleaning and Maintenance of the Non-Sterile Compounding Area"

5.0 DEFINITIONS

5.1 N/A

6.0 FREQUENCY

6.1 This procedure shall be followed when compounding in the non-sterile compounding area.

7.0 EQUIPMENT & SUPPLIES

7.1 Non-shedding garb

- 7.1.1 Disposable gown
- 7.1.2 Frock
- 7.1.3 Clean scrubs
- 7.1.4 Bouffant
- 7.1.5 Beard cover (if necessary)
- 7.1.6 Face mask
- 7.1.7 Booties
- 7.1.8 Eye protection (Mandatory!) – safety glasses or goggles (when doing acids, bases and milling)
- 7.1.8 Gloves
- 7.1.9 70% isopropyl alcohol (IPA) as sanitizing agent

8.0 GENERAL INFORMATION

8.1 Non-sterile compounding personnel must be properly gowned to protect product integrity.

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8.2 When compounding non-sterile preparations, gloves should be worn. Gloves must be sanitized with 70% IPA to prevent cross contamination.

8.3 Disposable gowns or frocks should close in the back or zip up in front. They should cover street garb completely and must have long sleeves with elastic wristbands.

8.4 Disposable gowns or frocks must be at least knee-length.

9.0 PROCEDURE

9.1 Prior to non-sterile compounding activities, all personnel must:

- 9.1.1 Put on a clean bouffant.
- 9.1.2 Put on a clean face mask and beard cover (if necessary).
- 9.1.3 Put on clean booties.
- 9.1.4 Put on a clean disposable gown (put thumb through the end of each sleeve on the disposable gown) or frock and assure it is completely closed.
- 9.1.5 Put on clean gloves and pull them completely up over the wrist bands.
- 9.1.6 Disinfect gloves with isopropyl gel and allow to air dry.
- 9.1.7 Before compounding spray gloves with 70% IPA and allow to air dry. Gloves should be continually sanitized during compounding to decrease potential for cross contamination.

9.2 If gloves are torn or punctured during compounding, remove and discard the damaged gloves and put on a clean pair per 9.1.5.

9.3 Upon exiting the non-sterile compounding area, remove gloves, disposable gown or frock, bouffant, face mask and booties. Gowns, bouffants and face masks can be re-used upon re-entry into the non-sterile compounding area.

10.0 ATTACHMENTS

10.1 N/A

11.0 HISTORY

Version Number	Date Effective	Description of Change	Change Request Number
1.0	03-08-06	New SOP	CR06047
2.0	07-26-07	Annual Review and SOP Changes	CR07002

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TITLE: NON-STERILE COMPOUNDING PROCESS VALIDATION	
SOP NUMBER: 9.130	**VERSION NUMBER: 2.0**
Non - Sterile Laboratory	Effective Date: 05-07-12
Originator:	
Reviewer:	

1.0 PURPOSE

1.1 The purpose of this procedure is to establish requirements for validation of the non-sterile compounding process.

2.0 SCOPE

2.1 This procedure applies to all non-sterile compounding personnel at New England Compounding Center.

3.0 RESPONSIBILITY

3.1 The Pharmacist-in-charge shall supervise this procedure and document that all non-sterile compounding personnel will comply with this procedure.

4.0 REFERENCES

4.1 USP Current Version <795> "Pharmaceutical Compounding – Non-Sterile Preparations"

4.2 SOP 2.040 "Non-Sterile Compounding Personnel Qualification"

4.3 SOP 9.040 "Compounder – The Compounder-Rx"

4.4 SOP 9.140 "Non-Sterile Compounding Finished Preparation Testing"

5.0 DEFINITIONS

5.1 Process Validation – method of evaluating a critical compounding process

6.0 FREQUENCY

6.1 Each non-sterile compounder shall perform this procedure at least annually. The Pharmacist-in-charge shall decide if more frequent testing is required.

7.0 EQUIPMENT & SUPPLIES

7.1 Contracted analytical testing laboratory (if applicable)

8.0 GENERAL INFORMATION

8.1 Process validations must be conducted without interruption and should mimic the process from weighing to packaging.

8.2 Process validations shall be performed under the most challenging or stressful conditions encountered during non-sterile compounding.

8.3 Analysts performing process validations should be scheduled at alternate times to avoid interruption of normal operation.

9.0 PROCEDURE

9.1 Refer to SOP 9.040, "Compounder – The Compounder-Rx"" for proper documentation of non-sterile compounded preparations.

9.2 Non-sterile compounds shall undergo finished preparation testing as per SOP 9.140, "Non-Sterile Compounding Finished Preparation Testing."

9.3 The Pharmacist-in-charge shall pick a compounded product prepared by the appropriate compounder at discretion.

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9.3.1 Review the Non-Sterile Compounding Validation Log (Attachment 1) to help select the product type. Compounders should perform process validations of several different products over time to assure multiple manipulations of compounding are challenged.

9.4 Perform potency testing using an appropriate method or contract lab.

9.5 Documentation Requirements

9.5.1 The Validation of Personnel – Non-Sterile Compounding forms (Attachments1 through 10, SOP 2.040, "Non-Sterile Compounding Personnel Qualification") shall include, but not be limited to the following items:

- 9.5.1.1 Compounders name
- 9.5.1.2 Date
- 9.5.1.3 Product name and type
- 9.5.1.4 Lot number and expiration date
- 9.5.1.5 Formulation Number
- 9.5.1.6 Acceptable potency range
- 9.5.1.7 Number of units filled
- 9.5.1.8 Volume per container

9.5.2 If a contract lab performs testing, a copy of the results shall be filed with the Validation of Personnel – Non-Sterile Compounding form in a quality assurance file.

9.6 Acceptance Criteria

9.6.1 Potency testing must meet the defined acceptance criteria (±10%) documented on Attachments 1 through 10 of SOP 2.040

9.6.2 All information must be recorded on the current compounding records.

9.6.3 All validation failures must have a formal investigation completed and personal will be retrained per SOP 2.040.

10.0 ATTACHMENTS

10.1 Attachment 1 – Non-Sterile Compounding Validation Log

11.0 HISTORY

Version Number	Date Effective	Description of Change	Change Request Number
1.0	03-08-06	New SOP	CR06048
20	05-07-12	New Updates	CR12004

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NON-STERILE COMPOUNDING VALIDATION LOG

Compounded By	Date	Drug Name	Drug Lot Number	Quantitative Test Results	Reviewed By

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TITLE: NON-STERILE COMPOUNDING FINISHED PREPARATION TESTING			
SOP NUMBER: 9.140		**VERSION NUMBER: 2.0**	
Non-Sterile Laboratory		Effective Date	02-28-08
Originator:			
Reviewer:			

1.0 PURPOSE

1.1 The purpose of this procedure is to establish requirements for finished preparation testing of non-sterile compounded preparations.

2.0 SCOPE

2.1 This procedure applies to all non-sterile compounding personnel at New England Compounding Center.

3.0 RESPONSIBILITY

3.1 The Pharmacist-in-charge shall supervise this procedure and document that all non-sterile compounding personnel responsible for finished preparation testing comply with this procedure.

4.0 REFERENCES

4.1 USP Current Version <795> "Pharmaceutical Compounding – Non-Sterile Preparations"

4.2 USP Current Version <1075> "Good Compounding Practices"

4.3 SOP 6.020 "Product Labeling"

4.4 SOP 9.050 "Beyond-Use Dating (BUD) of Compounded Preparations"

4.5 SOP 9.060 "Product Quarantine, Storage, Release and Disposal"

4.6 Massachusetts State Board of Pharmacy requirements

5.0 DEFINITIONS

5.1 N/A

6.0 FREQUENCY

6.1 Visual inspections occur on every non-sterile compounded product, by the non-sterile compounding staff and by a pharmacist prior to dispensing to patient or facility.

6.2 Quantitative analysis will be performed on an as needed basis to test a non-sterile compounding process.

7.0 EQUIPMENT & SUPPLIES

7.1 Third party analytical testing laboratory (if necessary)

8.0 GENERAL INFORMATION

8.1 This procedure is designed to outline visual inspection guidelines for all non-sterile compounded products.

8.2 All compounded products shall be quarantined until inspections are complete and all release requirements are met (see SOP 9.060, "Product Quarantine, Storage, Release and Disposal").

8.3 Document all third party testing results with Quality Control. When a sample is sent to the third party analytical testing lab, attach all documentation from contract labs to the original log sheet.

8.4 Quality Control will maintain records in the non-sterile Quality Control "Results" binder.

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9.0 PROCEDURE

9.1 Physical Testing Requirements

- 9.1.1 Finished liquid product shall be visually inspected for:
  - 9.1.1.1 Container leaks
  - 9.1.1.2 Clarity
  - 9.1.1.3 Solution cloudiness or phase separation
  - 9.1.1.4 Appropriate color
  - 9.1.1.5 Particulates
  - 9.1.1.6 Volume
- 9.1.2 Finished cream/gel products shall be visually inspected for:
  - 9.1.2.1 Container leaks
  - 9.1.2.2 Volume
  - 9.1.2.3 Color
  - 9.1.2.4 Stability/cracking
  - 9.1.2.5 Particulates
  - 9.1.2.6 Pharmaceutical elegance

9.2 Accuracy Requirements

- 9.2.1 All calculations shall be verified
- 9.2.2 All weights of ingredients shall be verified between the scale printout and the log sheet.

9.3 Identification and Potency Requirements

- 9.3.1 Verify the label has the correct:
  - 9.3.1.1 Name
  - 9.3.1.2 Amounts or concentrations of ingredients
  - 9.3.1.3 Total volume
  - 9.3.1.4 Beyond-use date
  - 9.3.1.5 Appropriate route(s) of administration
  - 9.3.1.6 Storage conditions
  - 9.3.1.7 Other safe use information as needed
- 9.3.2 Verify the compounding record to the original written order for correct identities of ingredients, purity of ingredients and amounts of ingredients.
- 9.3.3 Verify that correct fill volumes and quantities of units were prepared.

9.4 At the discretion of the Pharmacist-in-charge, samples shall be tested for potency using the appropriate method or samples shall be sent to a contract lab for testing. Samples that are awaiting potency results must be quarantined as per SOP 9.060, "Product Quarantine, Storage, Release and Disposal."

9.5 The Pharmacist- in- charge will determine when non-sterile samples are sent to the third party testing laboratory to test a compounding process.

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9.5.1 A sample (usually 10gm or ml) will be given to Quality Control along with the log sheet.

9.5.2 Results of the test will be kept on file in the appropriate Quality Control binder.

10.0 ATTACHMENTS

10.1 N/A

11.0 HISTORY

Version Number	Date Effective	Description of Change	Change Request Number
1.0	03-08-06	New SOP	CR06049
2.0	02-28-08	Removed section 9.2.3	CR08007

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